policies expressed in this policy statement, establish rates and charges that maximize the efficient utilization of the airport.

3.3 Relevant provisions of the Convention on International Civil Aviation (Chicago Convention) and many bilateral aviation agreements specify, inter alia, that charges imposed on foreign airlines must not be unjustly discriminatory, must not be higher than those imposed on domestic airlines engaged in similar international air services and equitably apportioned among categories of users. Charges that are inconsistent with these principles will be considered unjustly discriminatory or unfair and unreasonable.

3.5 Allowable costs—costs properly included in the rate base—must be allocated to aeronautical users by a transparent, reasonable and not unjustly discriminatory rate-setting methodology. The methodology must be applied consistently and cost differences must be determined quantitatively.

3.5.1 Common costs (costs not directly attributable to a specific user group or cost center) must be allocated according to a reasonable, transparent and not unjustly discriminatory cost allocation formula that is applied consistently.

Requirement of Financial Self-Sufficiency

4. Airport proprietors will maintain a fee and rental structure that in the circumstances of the airport makes the airport as financially self-sustaining as possible.

4.1 If market conditions or demand for air service do not permit the airport to be financially self-sustaining, the airport proprietor should establish long-term goals and targets to make the airport financially self-sustaining.

4.2 The federal obligation to make the airport as financially self-sustaining as possible does not justify the inclusion of environmental costs in the rate base unless an airport proprietor incurs actual costs.

Requirements Governing Revenue Application and Use

5. In accordance with relevant Federal statutory provisions governing the use of airport revenue, airport proprietors must keep airport revenue employed in the local airport system.

5.1 Whether or not total airport revenues exceed full current airport costs—

(a) aeronautical revenues may not exceed aeronautical costs; and

(b) the airport proprietor must keep all airport revenue and assets (aeronautical and non-aeronautical) employed in the local airport system in accordance with relevant Federal statutory provisions governing the use of airport revenue.

5.2 The progressive accumulation of substantial amounts of airport revenues may warrant an FAA inquiry into the airport proprietor's application of revenues to the local airport system.

5.3 The airport proprietor should consider the conversion of a reasonable amount of surplus airport revenues into airport improvements, which may include types of development that are not eligible for grants of funds under the Airport Improvement Program.

5.4 Indirect costs may not be included in the rate base unless they are based on a reasonable, transparent cost allocation formula calculated consistently for other units or cost centers of government.

5.5 If an airport proprietor generates a surplus from non-aeronautical sources, such revenue shall be expended in accordance with relevant Federal statutory provisions governing the use of airport revenue for the capital or operating costs of the airport, the local airport system, or other local facilities directly and substantially related to air transportation.

Issued in Washington, DC, on June 3, 1994.

Federico Peña,

Secretary of Transportation.

David R. Hinson,

Administrator, Federal Aviation Administration.

[FR Doc. 94–13943 Filed 6–3–94; 4:22 pm]

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Thursday
June 9, 1994

Part III

Department of Transportation

Federal Aviation Administration

14 CFR Parts 13 and 16
Rules of Practice for Federally Assisted Airport Proceedings; Proposed Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 13 and 16

[Docket No. 27783; Notice No. 94–18]

RIN 2120–AF–43

Rules of Practice for Federally Assisted Airport Proceedings

AGENCY: Federal Aviation Administration (FAA), (DOT).

ACTION: Notice of proposed rule (NPRM).

SUMMARY: This NPRM proposes to establish rules of practice for the filing of complaints and adjudication of compliance matters involving Federally assisted airports. The proposed rule would address exclusively airport compliance matters arising under the Airport and Airway Improvement Act (AAIA) of 1982, as amended; certain airport-related provisions of the Federal Aviation Act of 1958, as amended; the Surplus Property Act; as amended; predecessors to those acts; and regulations, grant agreements, and documents of conveyance issued or made under those acts. The proposed rule is intended to expedite substantially the handling and disposition of airport-related complaints, and to provide an efficient process for the agency to resolve disputes between air carriers and airport proprietors regarding whether airport fees and charges comply with Federal requirements. The NPRM would also amend the FAA's existing complaint and adjudication procedures, 14 CFR Part 13, "Investigative and Enforcement Procedures," to remove from the coverage of part 13 the airport-related matters that would be handled under the new part 16.

DATES: Comments must be received on or before August 8, 1994.

ADDRESSES: Comments on this notice may be mailed, in duplicate, to: Federal Aviation Administration, Office of the Chief Counsel, Attn.: Rules Docket (AGC–10), Docket No. 27783, 800 Independence Avenue, SW., Washington, DC 20591. Comments delivered must be marked Docket No. 27783. Comments may be examined in room 915F weekdays between 8:30 a.m. and 5 p.m. except on Federal holidays.

FOR FURTHER INFORMATION CONTACT: Barry Molar, Airport Law Branch (AGC–610), Office of the Chief Counsel, (202) 267–3473, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they desire. Comments relating to the economic effects that might result from adoption of the proposals contained in this notice are invited. Communications should identify the regulatory docket or notice number and be submitted in duplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 27783." The postcard will be dated and time stamped and returned to the commenter.

All communications received on or before the closing date for comments will be considered by the Administrator before taking action on the proposed rule. The proposal contained in the notice may be changed in light of comments received. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each substantive public contact with DOT/FAA personnel concerning this rulemaking will be filed in the docket.

Availability of NPRM

Any person may obtain a copy of this NPRM by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA–430, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–3464. Requests must identify the notice number of this NPRM. Persons interested in being placed on the mailing list for future NPRM's also should request a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes application procedures.

Background

In addition to its plenary responsibility for aviation safety, the Federal Aviation Administration (FAA) is responsible for administering Federal laws that impose certain economic requirements on the operation of airports in the National Aviation System. These laws include the Airport and Airway Improvement Act of 1982, as amended, (AAIA) which provides for Federal grants to airport sponsors and imposes conditions on the grants in the form of assurances by those sponsors; the Surplus Property Act, which provides for the transfer of Federal property to local governments for airport use and, like the AAIA, requires specific assurances from the sponsor for the use of the property; section 308(a) of the Federal Aviation Act of 1958, as amended (FAAct), which prohibits an airport operator from granting an exclusive operating right at an airport that has received Federal funds; and the Anti-Head Tax Act, section 1113(a)–(d) of the FAAct, which prohibits local taxes on air travel but expressly permits the imposition of reasonable fees.

The FAA, concurrently with the publication of this NPRM, has published for public comment a notice of proposed policy on the standards for determining whether airport rates and charges are "fair and reasonable" within the meaning of the above statutes. The FAA will refer to that policy statement, as revised after review of the comments received, in the implementation of these laws and in adjudicating complaints brought before the agency involving airport rates and charges.

The Secretary of Transportation and the FAA Administrator have the authority and responsibility to receive complaints and adjudicate matters of compliance with these statutes. Typically, complaints received by the FAA involve an allegation of economic discrimination toward an airport tenant or a claim that an exclusive right has been granted by the airport operator. However, two recent disputes between airlines serving a major airport and the airport operator indicate that the FAA may soon receive cases involving more complex rates and charges issues. In both cases, the airlines filed suit in court but did not file an administrative complaint with the FAA. In *Northwest Airlines, Inc., et al.* v. *County of Kent, Michigan*, the airline tenants at the Grand Rapids Airport challenged various aspects of a new rate structure at the airport. The Supreme Court issued a decision substantially in favor of the airport operator in January 1994. _____ U.S. _____, 62 U.S.L.W. 4103 (1994). In 1993, the Air Transport Association and tenant airlines at Los Angeles International Airport filed suit in U.S. District Court to challenge a substantial increase in landing fees at the airport. The District Court for the Central District of California dismissed the airline complaint in February 1994, citing among other things the lack of a private right of action for complaints under the Anti-Head Tax Act.

Even though no administrative complaint was filed in the Los Angeles case, the Department of Transportation

became involved after the City announced that airlines that did not pay the new fees would be barred from operation at the airport. In November 1993, Secretary of Transportation Federico Peña convened the parties to the dispute in Washington, DC, to assist in a settlement of the controversy. The product of the ensuing discussions was an agreement by the parties that permitted continued litigation of the issues without the threat of interruption of air service to the traveling public.

Shortly after the Los Angeles discussions, Secretary Peña issued a letter, dated December 10, 1993, outlining the Department's prospective policy on involvement in airport-airline fee disputes. The Secretary noted the significant potential impact on air travelers and on the national air transportation system of unresolved airport-airline disputes. While reaffirming the Department's historic reliance on good faith negotiations and agreement by the local parties, the Secretary announced a more active and engaged approach to disputes that could not be resolved at the local level. The letter included the Secretary's direction to the FAA to streamline the procedural rules for handling airport-airline fee disputes. In keeping with the approach announced by the Secretary, and the expressed need for a more effective, streamlined enforcement and adjudication procedure, the FAA proposes the adoption of a revised and updated procedural rule adapted specifically to the investigation and adjudication of airport-related complaints within the jurisdiction of the FAA.

Existing FAR Part 13

At present, enforcement of the requirements imposed on airport proprietors as a condition of the acceptance of Federal grant funds or property is accomplished through the administrative procedures set forth in 14 CFR part 13. Requirements include, without limitation: (a) The obligation to provide access to the airport on fair and reasonable terms without unjust discrimination; (b) the prohibition on grants of exclusive rights; (c) the obligation to use all airport revenue on capital or operating costs of the airport, the sponsor's airport system or other transportation projects directly related to air transportation, consistent with 49 U.S.C. App. 2210(a)(12); (d) the obligation to make the airport as self-sustaining as possible; (e) the obligation to ensure that, to the maximum extent practicable, at least 10 percent of concession businesses are small business concerns owned and operated by socially and economically disadvantaged businesses (DBE's); and (f) the obligations pursuant to section 505(d) of the AAIA that at least 10 percent of AIP funds shall be expended with DBE's.

The application of part 13 procedures to enforcement of airport grant agreements began in 1979, largely as the result of the enactment of a civil rights statute, Section 30 of the Airport and Airway Development Act, as amended (ADAP). Section 30, reenacted as section 520 in the AAIA, as amended, is similar to Title VI of the Civil Rights Act (CRA), but is not an amendment to the CRA. For this reason, the Title VI administrative process provided in 49 CFR part 21 does not cover section 520 cases, and it was necessary to provide another avenue of administrative process for compliance matters.

Accordingly, the FAA added ADAP to the list of statutes in part 13 under which the Administrator conducts investigations. In 1988, the FAA amended the applicability provisions of part 13 to refer to the Airport and Airway Improvement Act of 1982 (AAIA) and to the Airport and Airway Safety and Capacity Expansion Act of 1987.

While the scope of part 13 was thereby enlarged to accommodate a range of airport enforcement matters, no attempt was made to revise the complaint or hearing procedures to address the particular requirements of airport cases. In the late 1980's, the number and complexity of complaints from aeronautical users regarding airport sponsor compliance with grant assurances and other Federal obligations began to increase. In 1987, an amendment to the AAIA compressed the time available to the agency to reach a final decision in a case in which grant funds could be withheld. In effect, section 519 of the AAIA, as amended in 1987, prohibits the Secretary from denying a grant of entitlement funds or from withholding payments under a grant for more than 180 days without providing opportunity for a hearing and issuing a determination of a violation. Using the complex formal hearing procedures of subpart D of part 13, it would be practically impossible to meet the 180-day deadline in the statute for completion of the entire hearing and final decision process. The difficulty of meeting the 180-day deadline arises from a number of characteristics of part 13:

- There are no explicit deadlines for completion of the investigative phase of a complaint.
- There is no guidance or direction on the processing of complaints that are treated as reports of violations under § 13.1. The absence of procedures for processing such cases has led to delays in disposition of cases, confusion as to the status of regional determinations under § 13.1 as judicially appealable final agency orders, and confusion over the procedures and standards for obtaining FAA headquarters review of regional determinations under § 13.1.
- The lack of more streamline adjudicatory procedures has tended to encourage the practice of submitting out-of-channel appeals and pleas for action directly to the Administrator and Secretary of Transportation. The submission of these requests diverts agency resources from investigations and leads to confusion regarding the contents of the administrative record.
- Some elements of part 13 today do not facilitate an expedited and definitive finding on compliance. For example, multiple, potentially duplicative an drawn-out hearings and the current administrative review process for hearing officer's decisions under subpart D make timely decisionmaking exceedingly difficult.
- FAA experience with part 13 indicates that some provisions permit parties to prolong litigation once the FAA has initiated formal proceedings. Subpart D of part 13 includes, for example, open-ended subpoena provisions, and permits discovery and motions practice without time limit if the hearing officer chooses to allow it. Also, part 13 places no clear limits upon the successive filing of dispositive motions under § 13.49 by all parties.

Part 13, in short, does not provide a structure that regularly facilitates the final administrative disposition of airports-related cases within prescribed time limits, and cannot be relied upon to afford expedited resolution of disputes that may be needed in major airline-airport cases. For these purposes, and consistent with the Secretary's direction for a more streamlined process, a new procedural rule is necessary to focus exclusively on airport matters; to avoid duplicative and unnecessary steps; and to offer expeditious treatment, especially in cases with substantial potential impact on air transportation. In support of these objectives, the rules proposed here would:

1. Require parties to undertake serious attempts at informal resolution of their dispute prior to the filing of a complaint.

2. Focus administrative resources as a priority on resolving complaints which,

if not expeditiously resolved, may result in substantial adverse impact on air transportation.

3. Provide for a single complaint procedure, rather than for formal and "informal" complaints as in part 13. This will avoid duplicate complaints and investigations on the same subject.

4. Limit "standing" to persons directly and substantially affected by the specific dispute at issue, i.e. persons with a substantial actual and present interest in the outcome of an issue that is ripe for decision. Part 16 could not be used to obtain advisory opinions on speculative actions or academic questions.

5. Set clear time limits on the actions of all parties, including the agency, from the time a complaint is filed through final agency decision.

6. Provide procedural flexibility, e.g., to shorten time limits and eliminate procedural steps in a particular proceeding, consistent with fairness to those affected, where circumstances require special expedition.

7. Promote the likelihood of informal resolution of cases by the affected air carrier and airport parties without expensive formal hearings, by rendering a public initial agency determination of compliance in a short time frame.

8. Limit the number of formal pleadings and require that the documentary evidence relied upon by the parties be submitted promptly with the pleadings.

9. Require that parties serve all pleadings and documents on each other and the FAA, and use overnight or hand-delivery when the need for expeditious resolution of the matter is particularly acute.

10. Provide for an expedited process for investigatory hearings that will provide a full record, without undue complexity, regarding proposed increases in airport rates and charges in cases of particular significance.

11. Provide hearing procedures that permit the scope of each hearing to be tailored to the complexity and circumstances of the particular case, and rely on briefing and oral argument where there are no genuine issues of material fact in dispute.

12. Clearly establish the burden that each party must carry to make its case.

13. Limit *amicus* participation to the filing of briefs.

14. Prohibit interlocutory appeals and requests for reconsideration, and focus instead on an effective appeals process.

Subparts A through I of the proposed rule set forth a comprehensive procedure for the filing, investigation, and adjudication of complaints filed with the FAA against airports, and for appeal of agency decisions regarding such complaints. Subpart J of the proposed rule includes a special procedure for the receipt and investigation of complaints by airlines against an airport alleging that an airport fee increase is unreasonable or unjustly discriminatory.

The normal complaint procedure would result in an initial determination by the agency, within approximately six months of the filing of a complaint, whether the airport was in violation of its Federal obligations. This time period would include two round of responsive pleadings by the complainant and respondent, and a reasonably expeditious investigation and preparation of decision by the FAA.

The special subpart J procedure would result in an initial determination within 120 days of the complaint. Typically, this determination would be whether the challenged rate was fair and reasonable within the meaning of the relevant statutes. Under subpart J, the agency would appoint a presiding officer who will act independently to conduct an expedited investigatory hearing on the complaint. The presiding officer would then prepare a report of investigation for transmittal to the Assistant Administrator for Airports, who would consider the hearing record and report in issuing the initial determination of compliance.

Both the investigatory hearing under subpart J and the adjudicatory hearing under subpart F would provide an open and fair process for efficient and expedited consideration of complaints involving Federally funded airports. In both procedures, the time allowed for issuance of a compliance decision represents a considered balance between the interest in expedited resolution of disputes and the need for adequate time for investigation and deliberation before issuing agency decisions in these potentially complex cases. In subpart J, for example, the relatively short time provided for an interim determination on a complaint is sufficient to allow for oral investigatory hearing.

Within the constraints imposed by the effort achieve expedition, the investigatory hearing would provide complainants and airports the opportunity to develop the record before the FAA through streamlined procedures that permit cross-examination, adversary process, and limited discovery. In the atypical case in which an adjudicatory hearing would be held (under section 519 of the AAIA or section 1002 of the FAAct), the proposed hearing procedures are intended to permit the FAA to complete compliance hearings within 180 days, while assuring that a sponsor receives a fair hearing and opportunity to present evidence and argument to support its position. That process would provide substantial procedural safeguards, although it would not conform in every respect to the provisions of the Administrative Procedure Act (APA). The hearings mandated by section 519 of the AAIA and section 1002 of the FAAct are not an "agency adjudication required by statute to be determined on the record after opportunity for an agency hearing" within the meaning of section 554 of the APA. Accordingly, provisions of section 554 of the APA do not apply to the adjudicatory hearing proposed in this rule.

Description of the Proposed Rule

Subpart A—General Provisions

Subpart A would include provisions of general applicability to proceedings brought under part 16, definitions of terms used in the regulation, and a provision on separation of functions.

The regulation would apply to complaints, investigations and adjudications regarding compliance by airports with the following:

(a) Sections 308 and 1113 of the Federal Aviation Act of 1958, as amended, 49 U.S.C. App. 1347 and 1513;

(b) Obligations contained in grant-in-aid agreements (grant assurances) issued under airport financial assistance legislation enacted over the years, and obligations directly imposed by that legislation (including obligations relating to use of disadvantaged business enterprises); and

(c) Obligations contained in deeds of transfer for property transferred from the United States to airport proprietors (proposed section 16.1(a)).

The proposed regulation would also specify that if a grant assurance concerns a requirement that is within the authority of another Federal agency, that agency's administrative processes should be used and that the FAA would defer to the other Federal agency's authority (proposed § 16.1(b)). For example, the grant assurances require compliance with the Davis-Bacon Act relating to the payment of union-scale wages on Federally funded construction projects. Allegations of violation of the Davis-Bacon Act would continue to be adjudicated by the Department of Labor, not by the FAA under proposed part 16.

The proposed definitions (proposed section 16.3) are for the most part derived from the definitions of like or similar terms in 14 CFR part 13. The proposed definition of agency attorney

would specify the FAA attorneys who can be responsible for investigating and prosecuting complaints. To assure compliance with the proposed rules on separation of functions in cases that go on to hearings under proposed subpart F, attorneys holding certain positions and working in certain offices of the FAA would be precluded from functioning as agency attorneys at any stage of the proceedings. Such attorneys would be available to advise the FAA decisionmaker or to serve as a hearing officer.

The proposed definition of hearing officer would require the hearing officer to be an attorney. FAA attorneys holding certain positions and working in specific offices would be precluded from functioning as hearing officers to assure compliance with the proposed rule on separation of functions.

Proposed § 16.5, requiring the separation of prosecutorial and adjudicatory functions in hearings, is based on FAR § 13.203, relating to civil penalty adjudications. Separation of functions is not required by statute because hearings under part 16 would not be subject to APA hearing requirements; however, the separation is provided to promote confidence in the impartiality and integrity of decisions under the new procedures. Separation of prosecutorial and adjudicatory functions would be provided from the time of the issuance of an initial determination in all cases in which an opportunity for hearing is provided, including cases in which the respondent waives hearing and appeals the initial determination in writing to the Administrator. When separation applies, the Assistant Administrator for Airports would be considered as performing the investigatory and prosecutorial function and would not participate in the decision of the Administrator or hearing officer.

Subpart B—General Rules Applicable to Complaints, Proceedings, and Appeals Initiated by the FAA

This subpart would apply to all phases of the investigations and adjudications under this part.

Proposed § 16.11 would provide for expediting any portion of an investigation or adjudication. While the normal procedures in this proposal are designed to be completed efficiently, in some circumstances there is a need to resolve an issue even more quickly. The section would authorize the Assistant Administrator for Airports to take a variety of steps appropriate to the particulars of any given case. The section is intended to provide flexibility to adopt such special procedures to assure sufficiently rapid decisionmaking and procedural fairness in the circumstances of the individual case.

The proposed rules on filing and service of documents, computation of time, and motions (proposed §§ 16.13, 16.15, 16.17, and 16.19), are based on similar provisions in the Federal Rules of Civil Procedure, the Department's Rules of Practice in Proceedings (14 CFR part 302), the Rules of Practice in Civil Penalty Actions (14 CFR part 13 subpart G), and the National Transportation Safety Board's Rules of Practice in Air Safety Proceedings (49 CFR part 821). These rules have been used for many years, are well-know to the aviation bar, and have proven to be effective.

Subpart C—Special Rules Applicable to Complaints.

Under proposed § 16.21, a potential complainant, *i.e.*, a person directly affected by the alleged noncompliance, would be required to engage in good faith efforts to resolve the disputed matter informally with potentially responsible respondents before filing a complaint with the FAA under part 16. Informal resolution may include mediation, arbitration, use of a dispute resolution board, or other form of third-party assistance. The Department's preference for informal resolution in lieu of formal complaint to the FAA is clearly stated in the notice of proposed policy statement published concurrently with this proposed rule.

Under this section, it would be necessary for the potential complainant or his representative to certify that good faith efforts had been made to achieve informal resolution. To protect the parties, and for consistency with Rule 408 of the Federal Rules of Evidence, the certification would not include information on monetary or other settlement offers made but not agreed upon in writing.

Section 16.23 Complaints, Answers, and Other Documents

Section 16.23 would specify the information to be included in a complaint, the additional pleadings allowed and the information to be contained therein, and the method for filing a motion to dismiss. In addition, it would shift to the complainant and the respondent the burden of providing all available supporting documents on which they rely and serving them upon all parties as specified in § 16.15.

Finally, it would provide that the FAA will have 20 days to docket and review the complaint. In the event that the complaint is not dismissed, the FAA will notify both the complainant and named respondent in writing within 20 days after the complaint is received that an answer shall be filed within 20 days of the date of service of the notification. The complainant's reply is due within 15 days of the answer, and the respondent's rebuttal, if any, is due within 15 days of the reply.

Section 16.25 Dismissals

Complaints that clearly do not state a cause of action that warrants investigation by the jurisdiction of the Administrator, as well as those that do not come within the jurisdiction of the Administrator under the authorities set forth in this part, would be dismissed with prejudice, within 20 days after receipt of the complaint. As a final order of the agency, a dismissal would be appealable to a United States Court of Appeals.

Section 16.27 Incomplete Complaints

Section 16.27 deals with a second category of complaint—one which states a *prima facie* cause of action and falls within the jurisdiction of the Administrator but is deficient as to one or more of the filing requirements set forth in § 16.23(b). Incomplete complaints would be dismissed within 20 days after the receipt of the complaint, without prejudice. Since the complainant would be able to refile, this dismissal would not be appealable to the FAA decision-maker or to a United States Court of Appeals.

Section 16.29 Investigations

Under § 16.29, where the FAA finds reasonable grounds to investigate the matters described in a complaint, it would conduct an investigation. Where there is little dispute about factual matters, or where documentary submissions alone are deemed sufficient to make a record for decision, the investigation may consist entirely of a review of the arguments and materials submitted by the parties in pleadings, *i.e.*, the complaint, answer, reply, and rebuttal. The FAA may rely on this review for its initial determination on compliance. Because the FAA could rely exclusively on information and documentary evidence filed with the pleadings, parties would be expected to provide thorough submissions in order to protect their interests.

Alternatively, the FAA could supplement the submissions by requesting additional information from a party or by field investigation if appropriate. Further, if necessary information is not furnished voluntarily the FAA could use its authority under the FAAct and the AAIA to subpoena witnesses for deposition and production of documents. By permitting the FAA to

render its initial determination based on the pleadings and material submitted therein, this section in effect permits the grant of initial summary judgment.

Section 16.31 Initial Determinations After Investigations

Section 16.31 provides procedures for issuance of the FAA's initial determinations and orders, and for issuance of the final decision on appeal of the initial determination in cases that do not involve a hearing. The Assistant Administrator for Airports, or a designee, would issue an initial determination in every case in which the FAA investigates a complaint. The agency would be required to issue an initial determination in 120 days from the due date of the last pleading (*i.e.*, reply or rebuttal), but the date could be extended for up to 60 days for good cause, or due to delay caused by the complainant. If there is no appeal of the initial determination, it would become the final decision of the Administrator. If a party adversely affected by the initial determination does not file an administrative appeal, the FAA proposes that the final decision would not be judicially reviewable.

The initial determination is intended to provide a prompt and authoritative indication of the agency position on a complaint. Consistent with the view that local parties are best positioned to resolve disputes, the initial determination should provide guidance to airport proprietors and airport users in resolving the matter without further process. While the initial determination can be appealed, the FAA expects that in many instances the initial decision would resolve the issues raised in the complaint to the satisfaction of the parties. In such cases, the parties may find it more beneficial to negotiate a solution based on the FAA's initial position than to continue to litigate the matter.

Section 16.33 Final Decision Without Hearing

If the initial determination finds the sponsor in compliance and dismisses the complaint, the complainant could appeal the determination by a written appeal to the Administrator within 30 days. Reply briefs could be filed within 20 days, and the Administrator would be required to issue a final agency decision on appeal within 30 days of the due date for the reply briefs. The FAA would not provide opportunity for a hearing on the dismissal of a complaint.

If the initial determination contains a finding of noncompliance and the respondent is entitled to a hearing, the determination would provide the sponsor the opportunity elect an oral evidentiary hearing under subpart F. The procedure for electing or waiving a hearing is set forth in Subpart E. If the respondent waives hearing and instead elects to file a written appeal to the Administrator, a final decision would be issued by the Administrator or a designee under § 16.33.

Subpart D—Special Rules Applicable to Proceedings Initiated by the FAA

Section 16.101 would make clear the FAA's continuing authority to initiate its own investigation of any matter within the applicability of this part without having received a complaint, as authorized by section 313 and section 1002 of the Federal Aviation Act and section 519 of the Airport and Airway Improvement Act.

Section 16.103 serves three purposes: (1) To require a notice setting forth the specific areas of concern to the FAA, following the initiation of an investigation; (2) to establish the time limit for a response; and (3) to encourage and provide time for informal resolution. In the event the issues raised are not resolved informally, the FAA could proceed to issue an initial determination under § 16.31.

Subpart E—Proposed Orders of Compliance

Subpart E is similar to § 13.20 of part 13, but provides a more streamlined and expedited procedure for the sponsor to elect to exercise the option of requesting a hearing, in keeping with the purpose of proposed part 16. If the initial determination proposes a sanction against the sponsor subject to section 519(b) of the AAIA or section 1002 of the FAAct, the respondent could file a request for hearing within 30 days after service of the determination. If the respondent elects a hearing, the agency will issue a hearing order.

Alternatively, if the respondent waives hearing and instead files a written appeal (within 30 days), the Administrator would issue a final decision in accordance with the procedures set forth in § 16.33.

During the 30-day period before an election of hearing or written appeal is due, the respondent and complainant would be encouraged to negotiate a resolution of the dispute based on the initial determination.

If the respondent fails to respond, the initial determination becomes final.

Subpart F—Hearings

Proposed subpart F would state the procedures for initiating and conducting adjudicative hearings. The hearing order, issued by the Deputy Chief Counsel under proposed § 16.201, would set the scope of the hearing by identifying the issues to be resolved, as well as assigning the hearing officer.

If no material facts that require oral examination of witnesses are in dispute, the hearing could be limited to submission of briefs and oral argument. If the hearing follows an investigatory hearing under subpart J, the record from the subpart J proceeding would be made part of the adjudicative hearing record, and the hearing officer could limit the submission of evidence to avoid duplication of the prior proceeding.

In the hearing, the agency attorney would represent the agency's position before the hearing officer, and would have the same status as any other representative of a party.

The proposed rules include commonly used adjudicatory procedures such as representation of the parties by attorneys, intervention, participation by non-parties, pretrial procedures and discovery, the availability of compulsory process to obtain evidence, and procedures for use at the hearing. They are based on similar provisions in the Federal Rules of Civil Procedure, the Department's Rules of Practice in Proceedings (14 CFR Part 302), the Rules of Practice in Civil Penalty Actions (14 CFR part 13 subpart G), and the National Transportation Safety Board's Rules of Practice in Air Safety Proceedings (49 CFR part 821). These provisions are intended to provide the parties with a reasonable opportunity to prepare their cases, while allowing the process to be completed expeditiously.

Subpart G—Initial Decisions, Orders and Appeals

Proposed subpart G provides procedures for issuance of initial decisions and orders by hearing officers, appeals of the initial decision to the FAA decisionmaker and for the issuance of consent orders. Proposed § 16.241 governing initial decisions and administrative appeals is based on 14 CFR 13.20(g)–(i). However, shorter time periods are provided to accommodate the time limits of section 519 of the AAIA. In addition, the proposed rule would include a provision for *sua sponte* review of an initial decision by the FAA decisionmaker, consistent with the practice under 14 CFR 302.28(d).

Proposed § 16.243 governing disposal of cases by consent orders is derived from 14 CFR 13.13.

Subpart H—Judicial Review

Proposed Subpart H would contain rules applicable to judicial review of final agency orders. Proposed

§ 16.247(a) would set forth the basic authority to seek judicial review. The provision is based on 14 CFR 13.235. Specific reference to section 519(b)(4) of the AAIA has been added. Proposed § 16.247(b) would identify FAA decisions and actions under part 16 that the FAA does not consider to be judicially reviewable final agency orders.

Subpart I—Ex Parte Communications

The proposed rule on *ex parte* communications is based on subpart J of the Rules of Practice in Air Safety Proceedings of the NTSB, 49 CFR Part 821, subpart J.

Subpart J—Alternate Procedure for Certain Complaints Concerning Airport Rates and Charges

Proposed subpart J would provide a special procedure for the expedited resolution of certain significant disputes involving the fees that airport operators charge airlines. The procedure would involve a formal investigation, including an evidentiary investigative hearing. The concept of the investigatory hearing derives from subpart F of part 13. However, special provisions governing the conduct of discovery, hearing, and initial determination in the subpart J proceeding are intended to assure that the investigative process can be completed within the time frame provided in the rule. If the conditions for the use of subpart J are met, the airline filing the complaint could request either the subpart J procedure or the investigatory procedures under § 16.29.

Proposed § 16.401 sets forth the conditions necessary to request the special procedure. A subpart J proceeding would be available only to carriers holding authority under sections 401, 402, or 418 of the FAAct or operating under an exemption for scheduled service under 14 CFR part 298.

A complaint requesting subpart J procedures would have to meet the general requirements of Part 16 and the complainant would have to request the use of subpart J procedures. In addition, subpart J would only be available for a complaint alleging that an increase in an airport rate or charge is unreasonable or unjustly discriminatory. The request would be granted if the Assistant Administrator for Airports determines that the complaint involves an issue that if not resolved in an expedited manner could have a significant adverse impact on air transportation. The FAA also proposes that subpart J could be used when the Assistant Administrator for Airports determines that a complaint raises a significant policy issue, without regard to the significance of the potential impacts of the case.

The subpart J proceeding would be more than usually resource-intensive for the agency, because of the expedited schedule and the formal investigatory hearing. The limitation of complainants under subpart J to scheduled air carriers and the limitation of the subject matter to significant disputes over airport fees is intended, therefore, to limit use of agency resources for an expedited hearing procedure to those cases that have the greatest potential effect on the traveling public.

Section 16.403 would establish requirements for the filing of complaints and would establish procedures for ruling on the request for use of subpart J procedures. The Administrator would rule on the request for use of subpart J procedures within seven days. If the complaint did not meet the requirements for use of subpart J but otherwise satisfied part 16, the complaint would be processed under subparts B and C exclusively.

If the Assistant Administrator for Airports determined to employ subpart J procedures, the respondents would be required to file an answer within 21 days of the Administrator's notice.

Under § 16.405, the Assistant Administrator for Airports would issue a notice and order of investigation within seven days after the answer is served. The notice and order of investigation would identify the presiding officer for the investigation, the allegations and scope of investigation and the date by which the presiding officer is directed to issue a report of investigation. The report will generally be due 60 days after the answer was filed. Under § 16.407, the presiding officer may not be an agency attorney, as defined in subpart A, or a person otherwise involved in the investigation of airport compliance matters. Accordingly, while the presiding officer could be an FAA or other DOT attorney, or another FAA employee with experience relevant to the issue, the presiding officer would not be a person with any prior involvement in the case at hand or a person whose regular duties involved enforcement of airport compliance.

Proposed § 16.411 sets forth procedures for a subpart J investigation, including an expedited investigatory hearing. The procedures are derived from existing part 13 and the hearing procedures in proposed part 16, subpart F.

Proposed § 16.413 would require the preparation of a report of investigation which would be provided to the Assistant Administrator and served on the parties. Under proposed § 16.415, the Assistant Administrator would issue an initial determination after review of the record developed in the investigation, including the presiding officer's report. The initial determination would be appealable to the Administrator or his designee under the provisions of § 16.31.

Proposed § 16.415 would provide for automatic suspension, 30 days after the initial determination, of eligibility to receive new Airport Improvement Program grants or payments under existing grants if the initial determination finds that the challenged rate or charge is unreasonable or unjustly discriminatory. However, the suspension would be deferred if the respondent issued an appropriate rescission of the disputed rate or charge pending completion of the proceeding under part 16.

Request for Comments

Interested persons are invited to comment on any aspect of the proposed rules. The FAA is particularly interested in comment on the following issues:

1. Whether the proposed rule strikes the right balance between providing an opportunity to be heard, on the one hand, and producing an expeditious agency decision, on the other.
2. Whether the overall time frames provided from complaint to initial agency determination and from appeal to final agency decision are practical.
3. Whether the particular time limits provided for each procedural step are adequate.
4. The placement of responsibility for investigation, hearing, and adjudication of complaints received by the FAA.

Regulatory Evaluation Summary

This notice proposes to adopt a new procedure for the filing, investigation, and adjudication of complaints against airports for violation of certain statutes administered by the FAA. The new procedures would be substituted for existing procedures under 14 CFR part 13. While the proposed rule differs in many details from the existing rule, the costs to a complainant and respondent involved in the complaint process would be virtually identical to the costs involved under the existing rule. Accordingly, the expected economic impact of this proposed amendment would be so minimal that a full Regulatory Evaluation is not warranted.

International Trade Impact Statement

This rule is not anticipated to affect the import of foreign products or

services into the United States or the export of U.S. products or services to foreign countries.

Regulatory Flexibility Determination

The Regulatory Flexibility Act (RFA) of 1980 was enacted by Congress to ensure that small entities are not unnecessarily or disproportionately burdened by Government regulations. The RFA requires a Regulatory Flexibility Analysis if a rule would have a significant economic impact, either detrimental or beneficial, on a substantial number of small entities. Based on the potential relief that the rule will provide and the criteria of implementing FAA Order 2100.14A, Regulatory Flexibility Criteria and Guidance, the FAA has determined that the rule will not have a significant economic impact on a substantial number of small entities.

Federalism Implications

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Paperwork Reduction Act

This proposed rule contains no information collection requirements that require approval of the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1980 (44 U.S.C. 3507 *et seq.*)

Conclusion

For the reasons discussed in the preamble, and based on the findings in the Regulatory Flexibility Determination and the International Trade Analysis, the FAA has determined that this proposed regulation is not economically significant under Executive Order 12866. However, due to the public interest in this rulemaking, this proposed rule is considered significant under the Executive Order. The FAA certifies that this proposal, if adopted, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. This proposal is considered significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1978).

List of Subjects

14 CFR Part 13

Enforcement procedures, Investigations, Penalties.

14 CFR Part 16

Enforcement procedures, Investigations.

The Proposed Amendments

Accordingly, the Federal Aviation Administration proposes to amend part 13 and adopt new part 16 of the Federal Aviation Regulations (14 CFR parts 13 and 16) as follows:

PART 13—INVESTIGATIVE AND ENFORCEMENT PROCEDURES

1. The authority citation for part 13 continues to read as follows:

Authority: 49 U.S.C. 106(g) and 322; 49 U.S.C. App. 1354(a) and (c), 1374(d), 1401–1406, 1421–1432, 1471–1473, 1481, 1482, 1484–1489, 1523, 1655(c), 1808–1810, 2157(e) and (f), 2218, 2219; 16 U.S.C. 6002, 6004; 49 CFR 1.47.

2. Section 13.3 is amended by adding paragraph (d), to read as follows:

§ 13.3 Investigations (general).

* * * * *

(d) A complaint against the sponsor, proprietor, or operator of a Federally-assisted airport shall be filed in accordance with the provisions of part 16 of this chapter. Notwithstanding other provisions of this part, complaints, investigations, and agency decisions involving violations of the legal authorities listed in § 16.1 of this chapter are governed exclusively by the provisions of part 16 of this chapter.

3. A new part 16 is added to read as follows:

PART 16—RULES OF PRACTICE FOR FEDERALLY ASSISTED AIRPORT ENFORCEMENT PROCEEDINGS

Subpart A—General Provisions

Sec.

Subpart B—General Rules Applicable to Complaints, Proceedings Initiated by the FAA, and Appeals

Subpart C—Special Rules Applicable to Complaints

Subpart D—Special Rules Applicable to Proceedings Initiated by the FAA

Subpart E—Proposed Orders of Compliance

Subpart F—Hearings

Subpart G—Initial Decisions, Orders and Appeals

Subpart H—Judicial Review

Subpart I—Ex Parte Communications

Subpart J—Alternate Procedure for Certain Complaints Concerning Airport Rates and Charges

Authority: 49 U.S.C. 106(g), 322; 49 U.S.C. 1110, 1111, and 1115; 49 U.S.C. App. 1349

(a) and (c), 1354 (a) and (c), 1482 (a), (b) and (c), 1486, and 1513 (a) through (d) and (f); 49 U.S.C. 1718 (a) and (b), 1719, 1723, 1726 and 1727; 49 U.S.C. App. 2204 (a), (b), (c), (d) and (h), 2210(a), 2211(a), 2215, 2218, 2219, and 2222(c); 50 U.S.C. App. 1622(g); 49 U.S.C. App. 1655(c); 49 CFR 1.47.

Subpart A—General Provisions

§ 16.1 Applicability and description of part.

(a) *General.* The provisions of this part govern all proceedings involving Federally-assisted airports, whether the proceedings are instituted by order of the FAA or by filing with the FAA of a complaint, under the following authorities:

(1) Section 308 of the Federal Aviation Act of 1958, as amended, 49 U.S.C. App. 1349, prohibiting the grant of exclusive rights for the use of any landing area or air navigation facility on which Federal funds have been expended.

(2) Requirements of the Anti-Head Tax Act, section 1113 (a) through (d) of the Federal Aviation Act, 49 U.S.C. App. 1513 (a)–(d).

(3) The assurances contained in grant-in-aid agreements issued under the Federal Airport Act of 1946, 49 U.S.C. 1101 *et seq.*

(4) The assurances contained in grant-in-aid agreements issued under the Airport and Airway Development Act of 1970, as amended, 49 U.S.C. 1701, *et seq.*

(5) The assurances contained in grant-in-aid agreements issued under the Airport and Airway Improvement Act of 1982, as amended, (AAIA) 49 U.S.C. App. 2201 *et seq.*, specifically section 511(a), 49 U.S.C. App. 2210(a).

(6) Section 505(d) of the Airport and Airway Improvement Act of 1982, as amended, 49 U.S.C. App. 2214(d).

(7) Obligations contained in property deeds for property transferred under to section 16 of the Federal Airport Act (49 U.S.C. 1115), section 23 of the Airport and Airway Development Act (49 U.S.C. 1723), or section 516 of the Airport and Airway Improvement Act (49 U.S.C. App. 2215).

(8) Obligations contained in property deeds for property transferred under the Surplus Property Act (50 U.S.C. 1622(g)).

(b) *Other agencies.* Where a grant assurance concerns a statute, executive order, regulation, or other authority that provides an administrative process for the investigation or adjudication of complaints by a Federal agency other than the FAA, complaints shall use the administrative process established by those authorities. Where a grant assurance concerns a statute, executive order, regulation, or other authority that enables a Federal agency other than the FAA to investigate, adjudicate, and enforce compliance under those authorities on its own initiative, the FAA may defer to that Federal agency.

(c) *Other enforcement.* If a complaint or action initiated by the FAA involves a violation of the Federal Aviation Act or FAA regulations, except as specified in paragraphs (a)(1) and (a)(7) of this section, the FAA may take investigative and enforcement action under 14 CFR part 13, "Investigative and Enforcement Procedures."

(d) *Effective date:* This part applies to a complaint filed with the FAA on or after [effective date of final rule].

§ 16.3 Definitions.

Terms defined in the Acts are used as so defined. As used in this part:

Act means a statute listed in § 16.1 of this part or any regulation, agreement, or document of conveyance issued or made under that statute.

Administrator means the Administrator or his designee.

Agency attorney means the Deputy Chief Counsel; the Assistant Chief Counsel and attorneys in the Airports/Environmental Law Division of the Office of the Chief Counsel; the Assistant Chief Counsel and attorneys in an FAA region or center who represent the FAA during the investigation of a complaint or at a hearing on a complaint, and who prosecute on behalf of the FAA, as appropriate. An agency attorney shall not include the Chief Counsel, the Assistant Chief Counsel for Litigation, or any attorney on the staff of the Assistant Chief Counsel for Litigation who advises the FAA decisionmaker regarding an initial decision of the hearing officer or any appeal to the decisionmaker or who is supervised in that action by a person who provides such advice in an action covered by this part.

Assistant Administrator means the Assistant Administrator for Airports.

Complainant means the person submitting a complaint.

Complaint means a written document meeting the requirements of this part filed with the FAA by a person directly and substantially affected by anything allegedly done or omitted to be done by any person in contravention of any provision of any Act, as defined in this section, as to matters within the jurisdiction of the Administrator.

FAA decisionmaker means the Administrator of the FAA or any person to whom the Administrator has delegated the authority to issue a final decision and order of the Administrator on appeal from the initial decision of a hearing officer.

File means to submit written documents to the FAA for inclusion in the Enforcement Docket or to a hearing officer or presiding officer as appropriate.

Final decision and order means a final agency decision on the disposition of a complaint or on a respondent's compliance with any Act, as defined in this section, and directs appropriate action. A final decision and order that finds noncompliance may direct any sanction authorized by applicable laws.

Hearing officer means an attorney designated by the FAA in a hearing order to serve as a hearing officer in a hearing under this part. The following are not designated as hearing officers: the Chief Counsel and Deputy Chief Counsel; the Assistant Chief Counsel and attorneys in the FAA region or center in which the noncompliance has allegedly occurred or is occurring; and the Assistant Chief Counsel and attorneys in the Airports and Environmental Law Division of the FAA Office of the Chief Counsel.

Initial decision means a decision made by the hearing officer in a hearing under subpart F of this part.

Initial determination means a non-final agency decision following an investigation, including an investigation by investigative hearing under subpart J of this part.

Mail means U.S. first class mail; U.S. certified mail; and U.S. Express mail.

Noncompliance means anything done or omitted to be done by any person in contravention of any provision of any Act, as defined in this section, as to matters within the jurisdiction of the Administrator.

Party means the complainant(s) and the respondent(s) named in the complaint and, when an initial determination providing an opportunity for hearing is issued under § 16.31 and subpart E of this part, the agency.

Person means an individual, professional or other association, business or other private organization, including a sole proprietorship, partnership, or corporation, or a State or any agency of a State, such as a municipality or other political subdivision of a State, a tax-supported organization, or an Indian tribe or pueblo.

Personal delivery means hand delivery or overnight express delivery service.

Presiding officer means a person designated by the Assistant Administrator to preside over the investigation provided in subpart J of this part, who is neither an agency attorney as defined in this section or a

person otherwise engaged in the investigation of airport compliance.

Respondent means any person named in a complaint as a person responsible for things done or omitted to be done in contravention of any provision of any Act as to matters within the jurisdiction of the Administrator.

Sponsor means:

(1) Any public agency which, either individually or jointly with one or more other public agencies, has received Federal financial assistance for airport development or planning under the Federal Airport Act, Airport and Airway Development Act or Airport and Airway Improvement Act.

(2) Any private owner of a public-use airport who has received financial assistance from the FAA for such airport; and

(3) Any person to whom the Federal government has conveyed property for airport purposes under section 13(g) of the Surplus Property Act of 1944, as amended.

§ 16.5 Separation of functions.

(a) Proceedings under this part, including hearings under subpart F of this part, will be prosecuted by an agency attorney.

(b) After issuance of an initial determination in which the FAA provides the opportunity for a hearing, an agency employee engaged in the performance of investigative or prosecutorial functions in a proceeding under this part will not, in that case or a factually related case, participate or give advice in an initial decision by the hearing officer, a final decision by the Administrator or designee on written appeal, or final decision by the FAA decisionmaker, and will not, except as counsel or as witness in the public proceedings, engage in any substantive communication regarding that case or a related case with the hearing officer, the Administrator on written appeal, the FAA decisionmaker, or agency employees advising those officials in that capacity.

(c) The Chief Counsel, the Assistant Chief Counsel for Litigation, or an attorney on the staff of the Assistant Chief Counsel for Litigation advises the FAA decisionmaker regarding an initial decision, an appeal, or a final decision regarding any case brought under this part.

Subpart B—General Rules Applicable to Complaints, Proceedings Initiated by the FAA, and Appeals

§ 16.11 Expedition and other modification of process.

Under the authority of 49 U.S.C. 1354(a) and 2218(a), the Assistant Administrator may conduct investigations, issue orders, and take such other actions as are necessary to fulfill the purposes of this part, including the extension of any time period prescribed where necessary or appropriate for a fair and complete hearing of matters before the agency. Notwithstanding any other provision of this part, upon finding that circumstances require expedited handling of a particular case or controversy, the Assistant Administrator may issue an order directing any of the following prior to the issuance of an initial determination:

(a) Shortening the time period for any action under this part consistent with due process;

(b) If other adequate opportunity to respond to pleadings is available, eliminating the reply, rebuttal, or other actions prescribed by this part;

(c) Authorizing a presiding officer to adopt expedited procedures;

(d) Designating alternative methods of service; or

(e) Directing such other measures as may be required.

§ 16.13 Filing of documents.

Except as otherwise provided in this part, documents shall be filed with the FAA during a proceeding under this part as follows:

(a) *Filing address.* Documents to be filed with the FAA shall be filed with the Office of the Chief Counsel, Attention: FAA Enforcement Docket (AGC–10), Federal Aviation Administration, 800 Independence Ave., SW., Washington, DC 20591. Documents to be filed with a hearing officer shall be filed at the address stated in the hearing order. Documents to be filed with a presiding officer shall be filed at the address stated in the notice of investigation.

(b) *Date and method of filing.* Filing of any document shall be by personal delivery or mail as defined in this part, or by facsimile (when confirmed by filing on the same date by one of the foregoing methods). Unless the date is shown to be inaccurate documents to be filed with the FAA shall be deemed to be filed on the date of personal delivery, on the mailing date shown on the certificate of service, on the date shown on the postmark if there is no certificate of service, on the send date shown on the facsimile (provided filing has been confirmed through one of the foregoing methods), or on the mailing date shown by other evidence if there is no certificate of service and no postmark.

(c) *Number of copies.* Unless otherwise specified, an executed original and three copies of each document shall be filed with the FAA Enforcement Docket. Copies need not be signed, but the name of the persons signing the original shall be shown. If a hearing order or notice and order of investigation has been issued in the case one of the three copies shall be filed with the hearing officer or presiding officer. If filing by facsimile, the facsimile copy does not constitute one of the copies required under this section.

(d) *Form.* Documents filed with the FAA shall be typewritten or legibly printed. In the case of docketed proceedings, the document shall include the docket number of the proceeding on the front page.

(e) *Signing of documents and other papers.* The original of every document filed shall be signed by the person filing it or the person's duly authorized representative. The signature shall serve as a certification that the signer has read the document and, based on reasonable inquiry and to the best of the signer's knowledge, information, and belief, the document is—

(1) Consistent with this part;

(2) Warranted by existing law or that a good faith argument exists for extension, modification, or reversal of existing law; and

(3) Not interposed for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of the administrative process.

(f) *Designation of person to receive service.* The initial document filed shall state on the first page the name, post office address, telephone number, and facsimile number, if any, of the person(s) to be served with documents in the proceeding. If any of these items change during the proceeding, the person shall promptly file notice of the change with the FAA Enforcement Docket and the hearing officer and shall serve the notice on all parties.

(g) *Docket numbers.* Each submission identified as a complaint under this part by the submitting person will be assigned a docket number.

§ 16.15 Service of documents on the parties and the agency.

Except as otherwise provided in this part, documents shall be served as follows:

(a) *Who must be served.* Copies of all documents filed with the FAA Enforcement Docket shall be served by the persons filing them on all parties to the proceeding. A certificate of service shall accompany all documents when they are tendered for filing and shall certify concurrent service on the FAA and all parties. Certificates of service

shall be in substantially the following form:

I hereby certify that I have this day served the foregoing [name of document] on the following persons at the following addresses and facsimile numbers (if also served by facsimile) by [specify method of service]:

[list persons, addresses, facsimile numbers]

Dated this _____ day of _____, 19 _____.

[signature], for [party]

(b) *Method of service.* Except as otherwise agreed by the parties and the hearing officer, the method of service is the same as set forth in § 16.13(b) for filing documents.

(c) *Where service shall be made.* Service shall be made to the persons identified in accordance with § 16.13(f). If no such person has been designated, service shall be made on the party.

(d) *Presumption of service.* There shall be a presumption of lawful service—

(1) When acknowledgment of receipt is by a person who customarily or in the ordinary course of business receives mail at the address of the party or of the person designated under § 16.13(f).

(2) When a properly addressed envelope, sent to the most current address submitted under § 16.13(f), has been returned as undeliverable, unclaimed, or refused.

(e) *Date of service.* The date of service shall be determined in the same manner as the filing date under § 16.13(b).

§ 16.17 Computation of time.

This section applies to any period of time prescribed or allowed by this part, by notice or order of the hearing officer or presiding officer, or by an applicable statute.

(a) The date of an act, event, or default, after which a designated time period begins to run, is not included in a computation of time under this part.

(b) The last day of a time period is included in a computation of time unless it is a Saturday, Sunday, or legal holiday for the FAA, in which case, the time period runs until the end of the next day that is not a Saturday, Sunday, or legal holiday.

(c) Whenever a party has the right or is required to do some act within a prescribed period after service of a document upon the party, and the document is served on the party by mail, 5 days shall be added to the prescribed period.

§ 16.19 Motions.

(a) *General.* An application for an order or ruling not otherwise specifically provided for in this part shall be by motion. Unless otherwise ordered by the agency, the filing of a motion will not stay the date that any action is permitted or required by this part.

(b) *Form and contents.* Unless made during a hearing, motions shall be made in writing, shall state with particularity the relief sought and the grounds for the relief sought, and shall be accompanied by affidavits or other evidence relied upon. Motions introduced during hearings may be made orally on the record, unless the hearing officer or presiding officer directs otherwise.

(c) *Answers to motions.* Except as otherwise provided in this part, or except when a motion is made during a hearing, any party may file an answer in support of or in opposition to a motion, accompanied by affidavits or other evidence relied upon, provided that the answer to the motion is filed within 10 days after the motion has been served upon the person answering, or any other period set by the hearing officer. Where a motion is made during a hearing, the answer and the ruling thereon may be made at the hearing, or orally or in writing within the time set by the hearing officer or presiding officer.

Subpart C—Special Rules Applicable to Complaints

§ 16.21 Pre-complaint resolution.

(a) Prior to filing a complaint under this part, a person directly and substantially affected by the alleged noncompliance shall initiate and engage in good faith efforts to resolve the disputed matter informally with those individuals or entities believed responsible for the noncompliance. These efforts at informal resolution may include, without limitation, at the parties' expense, mediation, arbitration, use of a dispute resolution board.

(b) A complaint under this part will not be considered unless the person or authorized representative filing the complaint certifies that he or she has engaged in substantial and reasonable good faith efforts to resolve the disputed matter informally prior to filing the complaint and that there appears no reasonable prospect for timely resolution of the dispute. This certification shall include a brief description of the party's efforts to obtain informal resolution but shall not include information on monetary or other settlement offers made but not agreed upon in writing by all parties.

§ 16.23 Complaints, answers, replies, rebuttals, and other documents.

(a) A person directly and substantially affected by any alleged noncompliance may file a complaint with the Administrator.

(b) Complaints filed under this part shall—

(1) State the name and address of each person who is the subject of the complaint and, with respect to each person, the specific provisions of each Act that the complainant believes was violated;

(2) Be served, in accordance with § 16.15 of this part, along with all documents then available in the exercise of reasonable diligence, offered in support of the complaint, upon all persons named in the complaint as persons responsible for the alleged action(s) or omission(s) upon which the complaint is based;

(3) Provide a concise but complete statement of the facts relied upon to substantiate each allegation;

(4) Describe how the complainant was directly and substantially affected by the things done or omitted to be done by the respondents; and

(5) Comply with any additional or special requirements of subpart J of this part, if the complaint is brought under subpart J of this part.

(c) Unless the complaint is dismissed pursuant to § 16.25 or § 16.27, the FAA notifies the complainant and respondents in writing within 20 days after the date the FAA receives the complaint that the complaint has been docketed and that respondents are required to file an answer within 20 days of the date of service of the notification.

(d) The respondent shall file an answer within 20 days of the date of service of the FAA notification.

(e) The complainant may file a reply within 15 days of the date of service of the answer.

(f) The respondent may file a rebuttal within 15 days of the date of service of the complainant's rebuttal.

(g) The answer, reply, and rebuttal shall, like the complaint, be accompanied by supporting documentation upon which the parties rely.

(h) The answer shall deny or admit the allegations made in the complaint or state that the person filing the document is without sufficient knowledge or information to admit or deny any allegation, and shall assert any affirmative defense.

(i) The answer, reply, and rebuttal shall each contain a concise but complete statement of the facts relied upon to substantiate the answers, admissions, denials, or averments made.

(j) The respondent's answer may include a motion to dismiss the complaint, or any portion thereof, with a supporting memorandum of points and authorities. If a motion to dismiss

is filed, the complainant may respond as part of its rebuttal notwithstanding the 10-day time limit for answers to motions in § 16.19(c).

§ 16.25 Dismissals.

Within 20 days after the receipt of the complaint, the Assistant Administrator will dismiss a complaint, or any claim made in a complaint, with prejudice if it: Appears on its face to be outside the jurisdiction of the Administrator under the Acts listed in § 16.1; or on its face does not state a claim that warrants an investigation or further action by the FAA. The FAA will advise the person who filed the complaint or the person's duly authorized representative and the person(s) named in the complaint of the reasons for the dismissal.

§ 16.27 Incomplete complaints.

If a complaint is not dismissed pursuant to § 16.25, but is deficient as to one or more of the requirements set forth in § 16.21 or § 16.23(b), the Assistant Administrator will dismiss the complaint within 20 days after receiving it. Dismissal will be without prejudice to the refiling of the complaint after amendment to correct the deficiency. The FAA shall advise the person who filed the complaint or the person's duly authorized representative and the person(s) named in the complaint of the reasons for the dismissal.

§ 16.29 Investigations.

(a) If, based on the pleadings, there appears to be a reasonable basis for further investigation, the FAA investigates the subject matter of the complaint.

(b) The investigation may include one or more of the following, at the sole discretion of the FAA:

(1) A review of the written submissions or pleadings of the parties, as supplemented by any informal investigation the FAA considers necessary and by additional information furnished by the parties at FAA request. In rendering its initial determination, the FAA may rely entirely on the complaint and the responsive pleadings provided under this subpart, and each party shall file documents that it considers sufficient to present all relevant facts and argument necessary for the FAA to determine whether the sponsor is in compliance.

(2) Obtaining additional oral and documentary evidence by use of the agency's authority to compel production of such evidence under Section 313 of the Federal Aviation Act and Section 519 of the Airport and Airway Improvement Act. The Administrator's statutory authority to issue compulsory process has been delegated to the Chief Counsel, the Deputy Chief Counsel, the Assistant Chief Counsel for Airports and Environmental Law, and each Assistant Chief Counsel for a region or center.

(3) Conducting, or requiring that a sponsor conduct, an audit of airport financial records and transactions, as provided in 49 U.S.C. 2210(a)(11) and 2217.

§ 16.31 Initial determinations after investigations.

(a) After consideration of the pleadings and other information obtained by the FAA after investigation, the Assistant Administrator will render an initial determination and provide it to each party by certified mail within 120 days of the date the last pleading specified in § 16.23 was due. The time for issuing an initial determination may be extended for a period of up to 60 days upon a written determination by the Assistant Administrator that:

(1) The additional time is necessary for investigation and analysis of the matters in the complaint; or

(2) The investigation has been delayed by actions of a complainant.

(b) The initial determination will set forth a concise explanation of the factual and legal basis for the Assistant Administrator's determination on each claim made by the complainant.

(c) A party adversely affected by the initial determination may appeal the initial determination to the Administrator as provided in § 16.33.

(d) If the initial determination finds the respondent in noncompliance and proposes the issuance of a compliance order, the initial determination will include notice of opportunity for a hearing under subpart F of this part. The respondent may elect or waive a hearing as provided in subpart E of this part.

§ 16.33 Final decisions without hearing.

(a) The Administrator will issue a final decision on appeal from an initial determination, without a hearing, where—

(1) The complaint is dismissed after investigation;

(2) A hearing is not required by statute and is not otherwise made available by the FAA; or

(3) The FAA provides opportunity for a hearing to the respondent and the respondent waives the opportunity for a hearing as provided in subpart E of this part.

(b) In the cases described in paragraph (a) of this section a party adversely affected by the initial determination may file an appeal with the Administrator within 30 days after the date of service of the initial determination.

(c) A reply to an appeal may be filed with the Administrator within 20 days after the date of service of the appeal.

(d) The Administrator will issue a final decision and order within 30 days after the due date of the reply.

(e) If no appeal is filed within the time period specified in paragraph (b) of this section, the initial determination becomes the final decision and order of the FAA without further action. An initial determination that becomes final because there is no administrative appeal is not judicially reviewable.

Subpart D—Special Rules Applicable to Proceedings Initiated by the FAA

§ 16.101 Basis for the initiation of agency action.

The FAA may initiate its own investigation of any matter within the applicability of this part without having received a complaint. The investigation may include, without limitation, any of the actions described in § 16.29(b).

§ 16.103 Notice of investigation.

Following the initiation of an investigation under § 16.101 of this part, the FAA sends a notice to the person(s) subject to investigation. The notice will set forth the areas of the agency's concern and the reasons therefor; request a response to the notice within 30 days of the date of service; and inform the respondent that the FAA will, in its discretion, invite good faith efforts to resolve the matter.

§ 16.105 Failure to resolve informally.

If the matters addressed in the FAA notices are not resolved informally, the FAA may issue an initial determination under § 16.31.

Subpart E—Proposed Orders of Compliance

§ 16.109 Orders terminating eligibility for grants, cease and desist orders, and other compliance orders.

This section applies to initial determinations issued under § 16.31 that provide the opportunity for a hearing.

(a) The agency will provide the opportunity for a hearing if, in the initial determination, the agency proposes to issue an order terminating eligibility for grants, an order suspending the payment of grant funds, a cease and desist order, an order directing the refund of fees unlawfully collected, or any other compliance order issued by the Administrator to carry out the provisions of the Acts. In cases in which a hearing is not required by statute, the FAA may provide

opportunity for a hearing at its discretion.

(b) In a case in which the agency provides the opportunity for a hearing, the initial determination issued under § 16.31 will include a statement of the availability of a hearing under subpart F of this part.

(c) Within 30 days after service of an initial determination under § 16.31 and paragraph (b) of this section, a person subject to the proposed compliance order may—

(1) Request a hearing under subpart F of this part;

(2) Waive hearing and appeal the notice in writing to the Administrator, as provided in § 16.33;

(3) File, jointly with the complainant, a motion to withdraw the complaint and to dismiss the proposed compliance action; or

(4) Submit, jointly with the agency attorney, a proposed consent order under § 16.243(e).

(d) If the respondent fails to request a hearing or to file an appeal in writing within the time periods provided in paragraph (c) of this section, the initial determination becomes final.

Subpart F—Hearings

§ 16.201 Notice and order of hearing.

(a) If a respondent is provided the opportunity for hearing in an initial determination and does not waive hearing, the Deputy Chief Counsel within 10 days after the respondent elects a hearing will issue and serve on the respondent a hearing order. The hearing order will set forth:

(1) The allegations in the complaint, and the chronology and results of the investigation preliminary to the hearing;

(2) The relevant statutory, judicial, regulatory, and other authorities;

(3) The issues to be decided;

(4) Such rules of procedure as may be necessary to supplement the provisions of this part;

(5) The name and address of the person designated as hearing officer, and the assignment of authority to the hearing officer to conduct the hearing in accordance with the procedures set forth in this part;

(6) The date by which the hearing officer is directed to issue an initial decision.

(b) Where there are no genuine issues of material fact requiring oral examination of witnesses, the hearing order may contain a direction to the hearing officer to conduct a hearing by submission of briefs and oral argument without the presentation of testimony or other evidence.

§ 16.202 Powers of a hearing officer.

In accordance with the rules of this subpart, a hearing officer may:

(a) Give notice of, and hold, prehearing conferences and hearings;

(b) Administer oaths and affirmations;

(c) Issue subpoenas authorized by law and issue notices of deposition requested by the parties;

(d) Rule on offers of proof;

(e) Receive relevant and material evidence;

(f) Regulate the course of the hearing in accordance with the rules of this part to avoid unnecessary and duplicative proceedings in the interest of prompt and fair resolution of the matters at issue;

(g) Hold conferences to settle or to simplify the issues by consent of the parties;

(h) Dispose of procedural motions and requests;

(i) Examine witnesses; and

(j) Make findings of fact and conclusions of law, and issue an initial decision.

§ 16.203 Appearances, parties, and rights of parties.

(a) *Appearances.* Any party may appear and be heard in person.

(1) Any party may be accompanied, represented, or advised by an attorney licensed by a state, the District of Columbia, or a territory of the United States to practice law or appear before the courts of that state or territory.

(2) An attorney who represents a party shall file a notice of appearance in accordance with § 16.15(f).

(b) *Parties and agency participation.*

(1) The parties to the hearing are the respondent(s) named in the hearing order, and the agency.

(2) Unless otherwise specified in the hearing order, the agency attorney will serve as prosecutor for the agency from the date of issuance of the initial determination providing an opportunity for hearing.

(3) As appropriate to the issues raised in a particular case, offices and services of the FAA and the Office of the Secretary may assist the FAA attorney consistent with the provisions of § 16.5.

§ 16.207 Intervention and other participation.

(a) A person may submit a motion for leave to intervene as a party. Except for good cause shown, a motion for leave to intervene shall be submitted not later than 10 days after the notice of hearing and hearing order.

(b) If the hearing officer finds that intervention will not unduly broaden the issues or delay the proceedings and, if the person has a property or financial interest that may not be addressed adequately by the parties, the hearing officer may grant a motion for leave to intervene. The hearing officer may determine the extent to which an intervenor may participate in the proceedings.

(c) Other persons may petition the hearing officer for leave to participate in the hearing. Participation is limited to the filing of post-hearing briefs and reply to the hearing officer and the decisionmaker. Such briefs shall be filed and served on all parties in the same manner as the parties' post hearing briefs are filed.

(d) Participation under this section is at the discretion of the FAA, and no decision permitting participation shall be deemed to constitute an expression by the FAA that the participant has such a substantial interest in the proceeding as would entitle it to judicial review of such decision.

§ 16.209 Extension of time.

(a) *Extension by oral agreement.* The parties may agree to extend for a reasonable period the time for filing a document under this part. If the parties agree, the hearing officer shall grant one extension of time to each party. The party seeking the extension of time shall submit a draft order to the hearing officer to be signed by the hearing officer and filed with the hearing docket. The hearing officer may grant additional oral requests for an extension of time where the parties agree to the extension.

(b) *Extension by motion.* A party shall file a written motion for an extension of time with the hearing officer not later than 7 days before the document is due unless good cause for the late filing is shown. A party filing a written motion for an extension of time shall serve a copy of the motion on each party.

(c) *Failure to rule.* If the hearing officer fails to rule on a written motion for an extension of time by the date the document was due, the motion for an extension of time is deemed denied.

(d) *Effect on time limits.* If the hearing officer grants an extension of time as a result of oral agreement by the parties as specified in paragraph (a) of this section or, if the hearing officer grants an extension of time as a result of the sponsor's failure to adhere to the hearing schedule, the due date for the hearing officer's initial decision and for the final agency decision are extended by the length of the extension by the hearing officer, in accordance with section 519(b) of the AAIA, as amended in 1987.

§ 16.211. Prehearing conference.

(a) *Prehearing conference notice.* The hearing officer schedules a prehearing conference and serves a prehearing conference notice on the parties promptly after being designated as a hearing officer.

(1) The prehearing conference notice specifies the date, time, place, and manner (in person or by telephone) of the prehearing conference.

(2) The prehearing conference notice may direct the parties to exchange proposed witness lists, requests for evidence and the production of documents in the possession of another party, responses to interrogatories, admissions, proposed procedural schedules, and proposed stipulations before the date of the prehearing conference.

(b) *The prehearing conference.* The prehearing conference is conducted by telephone or in person, at the hearing officer's discretion. The prehearing conference addresses matters raised in the prehearing conference notice and such other matters as the hearing officer determines will assist in a prompt, full and fair hearing of the issues.

(c) *Prehearing conference report.* At the close of the prehearing conference, the hearing officer rules on any requests for evidence and the production of documents in the possession of other parties, responses to interrogatories, and admissions; on any requests for depositions; on any proposed stipulations; and on any pending applications for subpoenas as permitted by § 16.219. In addition, the hearing officer establishes the schedule, which shall provide for the issuance of an initial decision not later than 120 days after issuance of the initial determination order unless otherwise provided in the hearing order.

§ 16.213 Discovery.

Discovery is limited to requests for admissions, requests for production for documents, interrogatories, and depositions as authorized by § 16.215.

§ 16.215 Depositions.

(a) *General.* For good cause shown, the hearing officer may order that the testimony of a witness may be taken by deposition and that the witness produce documentary evidence in connection with such testimony. Generally, an order to take the deposition of a witness is entered only if:

(1) The person whose deposition is to be taken would be unavailable at the hearing; or

(2) The deposition is deemed necessary to perpetuate the testimony of the witness; or

(3) The taking of the deposition is necessary to prevent undue and excessive expense to a party and will not result in undue burden to other parties or in undue delay.

(b) *Application for deposition.* Any party desiring to take the deposition of a witness shall make application therefor to the hearing officer in writing, with a copy of the application served on each party. The application shall include:

(1) The name and residence of the witness;

(2) The time and place for the taking of the proposed deposition;

(3) The reasons why such deposition should be taken; and

(4) A general description of the matters concerning which the witness will be asked to testify.

(c) *Order authorizing deposition.* If good cause is shown, the hearing officer, in his or her discretion, issues an order authorizing the deposition and specifying the name of the witness to be deposed, the location and time of the deposition and the general scope and subject matter of the testimony to be taken.

(d) *Procedures for deposition.* (1) Witnesses whose testimony is taken by deposition shall be sworn or shall affirm before any questions are put to them. Each question propounded shall be recorded and the answers of the witness transcribed verbatim.

(2) Objections to questions or evidence shall be recorded in the transcript of the deposition. The interposing of an objection shall not relieve the witness of the obligation to answer questions, except where the answer would violate a privilege.

(3) The written transcript shall be subscribed by the witness, unless the parties by stipulation waive the signing or the witness is ill or cannot be found or refuses to sign. The reporter shall note the reason for failure to sign.

§ 16.217 Witnesses.

(a) Each party may designate as a witness any person who is able and willing to give testimony that is relevant and material to the issues in the hearing case, subject to the limitation set forth in paragraph (b) of this section.

(b) The hearing officer may exclude testimony of witnesses that would be irrelevant, immaterial, or unduly repetitious.

(c) Any witness may be accompanied by counsel. Counsel representing a nonparty witness has no right to examine the witness or otherwise participate in the development of testimony.

§ 16.219 Subpoenas.

(a) *Request for subpoena.* A party may apply to the hearing officer, within the time specified for such applications in the prehearing conference report, for a subpoena to compel testimony at a hearing or to require the production of documents only from the following persons:

(1) Another party;

(2) An officer, employee or agent of another party;

(3) Any other person named in the complaint as participating in or benefiting from the actions of the respondent alleged to have violated any Act; or

(4) An officer, employee or agent of any other person named in the complaint as participating in or benefiting from the actions of the respondent alleged to have violated any Act.

(b) *Issuance and service of subpoena.* (1) The hearing officer issues the subpoena if the hearing officer determines that the evidence to be obtained by the subpoena is relevant and material to the resolution of the issues in the case.

(2) Subpoenas shall be served by personal service, or upon an agent designated in writing for the purpose, or by registered or certified mail addressed to such person or agent. Whenever service is made by registered or certified mail, the date of mailing shall be considered at the time when service is made.

(3) A subpoena issued under this part is effective throughout the United States or any territory or possession thereof.

(c) *Motions to quash or modify subpoena.* (1) A party or any person upon whom a subpoena has been served may file a motion to quash or modify the subpoena with the hearing officer at or before the time specified in the subpoena for the filing of such motions. The applicant shall describe in detail the basis for the application to quash or modify the subpoena including, but not limited to, a statement that the testimony, document, or tangible evidence is not relevant to the proceeding, that the subpoena is not reasonably tailored to the scope of the proceeding, or that the subpoena is unreasonable and oppressive.

(2) A motion to quash or modify the subpoena stays the effect of the subpoena pending a decision by the hearing officer on the motion.

§ 16.221 Witness fees.

(a) The party on whose behalf a witness appears is responsible for paying any witness fees and mileage expenses.

(b) Except for employees of the United States summoned to testify as to matters related to their public employment, witnesses summoned by subpoena shall be paid the same fees and mileage expenses as are paid to a witness in a court of the United States in comparable circumstances.

§ 16.223 Evidence.

(a) *General.* A party may submit direct and rebuttal evidence in accordance with this section.

(b) *Requirement for written testimony and evidence.* Except in the case of evidence obtained by subpoena, or in the case of a special ruling by the hearing officer to admit oral testimony, a party's direct and rebuttal evidence shall be submitted in written form, in advance of the oral hearing pursuant to the schedule established in the hearing officer's prehearing conference report. Written direct and rebuttal fact testimony shall be certified by the witness as true and correct. Subject to the same exception (for evidence obtained by subpoena or subject to a special ruling by the hearing officer), oral examination of a party's own witness is limited to certification of the accuracy of written evidence, including correction and updating, if necessary, and reexamination following cross-examination by other parties.

(c) *Subpoenaed testimony.* Testimony of witnesses appearing under subpoena may be obtained orally.

(d) *Cross-examination.* A party may conduct cross-examination that may be required for disclosure of the facts, subject to control by the hearing officer for fairness, expedition, and exclusion of extraneous matters.

(e) *Hearsay evidence.* Hearsay evidence is admissible in proceedings governed by this part. The fact that evidence is hearsay goes to the weight of evidence and does not affect its admissibility.

(f) *Admission of evidence.* The hearing officer admits evidence introduced by a party in support of its case in accordance with this section, but may exclude irrelevant, immaterial or unduly repetitious evidence.

(g) *Expert or opinion witnesses.* An employee of the FAA or DOT may not be called as an expert or opinion witness for any party other than the agency except as provided in Department of Transportation regulations at 49 CFR part 9.

(h) *Subpart J hearing.* If an investigative hearing under subpart J was held on the complaint, the hearing officer may limit fact testimony and evidence in the hearing under this part to genuine issues of material fact not adequately developed in the record of the initial determination or not addressed in the initial determination.

§ 16.225 Public disclosure of evidence.

(a) Except as provided in this section, the hearing shall be open to the public.

(b) The hearing officer may order that any information contained in the record be withheld from public disclosure. Any person may object to disclosure of information in the record by filing a written motion to withhold specific information with the hearing officer. The person shall state specific grounds for nondisclosure in the motion.

(c) The hearing officer shall grant the motion to withhold information from public disclosure if the hearing officer determines that disclosure would be in violation of the Privacy Act, would reveal trade secrets or privileged or confidential commercial or financial information, or is otherwise prohibited by law.

§ 16.227 Standard of proof.

The hearing officer shall issue an initial decision or shall rule in a party's favor only if the decision or ruling is supported by, and in accordance with, reliable, probative, and substantial evidence contained in the record and is in accordance with law.

§ 16.229 Burden of proof.

(a) The burden of proof of noncompliance with an Act or any regulation, order, agreement or document of conveyance issued under the authority of an Act is on the agency.

(b) Except as otherwise provided by statute or rule, the proponent of a motion, request, or order has the burden of proof.

(c) A party who has asserted an affirmative defense has the burden of proving the affirmative defense.

§ 16.231 Offer of proof.

A party whose evidence has been excluded by a ruling of the hearing officer may offer the evidence on the record when filing an appeal.

§ 16.233 Record.

(a) *Subpart J investigation.* If a special hearing was held on the complaint under subpart J of this part, the pleadings, transcript of hearing, all exhibits received into evidence, all motions, applications, requests, and rulings, and all documents included in the hearing record and the report of the investigation are entered into the record of the hearing under this subpart.

(b) *Exclusive record.* The transcript of all testimony in the hearing, all exhibits received into evidence, all motions, applications, requests and rulings, and all documents included in the hearing record shall constitute the exclusive record for decision in the proceedings and the basis for the issuance of any orders.

(c) *Examination and copying of record.* Any interested person may examine the record at the Enforcement Docket, Federal Aviation Administration, 800 Independence Avenue, SW., room 924A, Washington, DC 20591. Any person may have a copy of the record after payment of reasonable costs for search and reproduction of the record.

§ 16.235. Argument before the hearing officer.

(a) *Argument during the hearing.* During the hearing, the hearing officer shall give the parties reasonable opportunity to present oral argument on the record supporting or opposing motions, objections, and rulings if the parties request an opportunity for argument. The hearing officer may direct written argument during the hearing if the hearing officer finds that submission of written arguments would not delay the hearing.

(b) *Posthearing briefs.* The hearing officer may request or permit the parties to submit posthearing briefs. The hearing officer may provide for the filing of simultaneous reply briefs as well, if such filing will not unduly delay the issuance of the hearing officer's initial decision. Posthearing briefs shall include proposed findings of fact and conclusions of law; exceptions to rulings of the hearing officer; references to the record in support of the findings of fact; and supporting arguments for the proposed findings, proposed conclusions, and exceptions.

§ 16.237 Waiver of procedures.

(a) The hearing officer shall waive such procedural steps as all parties to the hearing agree to waive before issuance of an initial decision.

(b) Consent to a waiver of any procedural step bars the raising of this issue on appeal.

(c) The parties may not by consent waive the obligation of the hearing officer to enter an initial decision on the record.

Subpart G—Initial Decisions, Orders and Appeals

§ 16.241 Initial decisions, orders, and appeals.

(a) The hearing officer shall issue an initial decision based on the record developed during the proceeding and shall send the initial decision to the parties not later than 120 days after the initial determination by the Assistant

Administrator unless otherwise provided in the hearing order.

(b) Each party adversely affected by the hearing officer's initial decision may file an appeal within 20 days of the date the initial decision is issued. Each party may file a reply to an appeal within 10 days after it is served on the party. Filing and service of appeals and replies shall be by personal delivery.

(c) If an appeal is filed, the FAA decisionmaker reviews the entire record and issues a final agency decision and order within 30 days after the due date for replies to the appeal(s). If no appeal is filed, the decisionmaker may take review of the case on his or her own motion. If the FAA decisionmaker finds that the respondent is not in compliance with any Act or any regulation, agreement, or document of conveyance issued or made under such Act, the final agency order includes a statement of corrective action, if appropriate, and identifies sanctions for continued noncompliance.

(d) If no appeal is filed, and the FAA decisionmaker does not take review of the initial decision on the FAA decisionmaker's own motion, the initial decision shall take effect as the final agency decision and order on the twenty-first day after the actual date the initial decision is issued.

(e) The failure to file an appeal is deemed a waiver of any rights to seek judicial review of an initial decision that becomes a final agency decision by operation of § 16.241(d).

(f) If the FAA decisionmaker takes review on the decisionmaker's own motion, the FAA decisionmaker issues a notice of review by the twenty-first day after the actual date the initial decision is issued.

(1) The notice sets forth the specific findings of fact and conclusions of law in the initial decision that are subject to review by the FAA decisionmaker.

(2) Parties may file briefs on review to the FAA decisionmaker or rely on their post-hearing briefs to the hearing officer. Briefs on review shall be filed not later than 15 days after service of the notice of review.

(3) The FAA decisionmaker issues a final agency decision and order within 30 days after the due date for briefs on review. If the FAA decisionmaker finds that the respondent is not in compliance with any Act or any regulation, agreement or document of conveyance issued under such Act, the final agency order includes a statement of corrective action, if appropriate, and identifies sanctions for continued noncompliance.

§ 16.243 Consent orders.

(a) The agency attorney and the respondents may agree at any time before the issuance of a final decision and order to dispose of the case by issuance of a consent order. Good faith efforts to resolve a complaint through issuance of a consent order may continue throughout the administrative process. Except as provided in § 16.209, such efforts may not serve as the basis for extensions of the times set forth in this part.

(b) A proposal for a consent order, specified in paragraph (a) of this section, shall include:

(1) A proposed consent order;

(2) An admission of all jurisdictional facts;

(3) An express waiver of the right to further procedural steps and of all rights to judicial review; and

(4) An incorporation by reference of the hearing order, if issued, and an acknowledgment that the hearing order may be used to construe the terms of the consent order.

(c) If the issuance of a consent order has been agreed upon by all parties to the hearing, the proposed consent order shall be filed with the hearing officer, along with a draft order adopting the consent decree and dismissing the case, for the hearing officer's adoption.

(d) The deadline for the hearing officer's initial decision and the final agency decision is extended by the amount of days elapsed between the filing of the proposed consent order with the hearing officer and the issuance of the hearing officer's order continuing the hearing.

(e) If the agency attorney and sponsor agree to dispose of a case by issuance of a consent order before the FAA issues a hearing order, the proposal for a consent order is submitted jointly to the official authorized to issue a hearing order, together with a request to adopt the consent order and dismiss the case. The official authorized to issue the hearing order issues the consent order as an order of the FAA and terminates the proceeding.

Subpart H—Judicial Review

§ 16.247 Judicial review of a final decision and order.

(a) A person may seek judicial review, in a United States Court of Appeals, of a final decision and order of the Administrator as provided in section 1006 of the Federal Aviation Act of 1958, as amended, or section 519(b)(4) of the Airport and Airway Improvement Act of 1982, as amended. A party seeking judicial review of a final decision and order shall file a petition for review with the Court not later than 60 days after a final decision and order under the AAIA has been served on the party or within 60 days after the entry of an order under the Federal Aviation Act.

(b) The following do not constitute final decisions and orders subject to judicial review:

(1) An FAA decision to dismiss a complaint without prejudice, as set forth in § 16.17;

(2) An initial determination issued by the Assistant Administrator;

(3) An initial decision issued by a hearing officer at the conclusion of a hearing;

(4) An initial determination or an initial decision of a hearing officer that becomes the final decision of the Administrator because it was not appealed within 30 days;

Subpart I—Ex Parte Communications

§ 16.301 Definitions.

As used in this subpart:

Decisional employee means the Administrator, Deputy Administrator, FAA decisionmaker, hearing officer, or other FAA employee who is or who may reasonably be expected to be involved in the decisional process of the proceeding;

Ex parte communication means an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given, but it shall not include requests for status reports on any matter or proceeding covered by this part.

§ 16.303 Prohibited ex parte communications.

(a) The prohibitions of this section shall apply from the time a proceeding is noticed for hearing unless the person responsible for the communication has knowledge that it will be noticed, in which case the prohibitions shall apply at the time of the acquisition of such knowledge.

(b) Except to the extent required for the disposition of ex parte matters as authorized by law:

(1) No interested person outside the FAA make or knowingly cause to be made to any decisional employee an ex parte communication relevant to the merits of the proceeding;

(2) No FAA employee shall make or knowingly cause to be made to any interested person outside the FAA an ex parte communication relevant to the merits of the proceeding; or

(3) Ex parte communications regarding solely matters of agency procedure or practice are not prohibited by this section.

§ 16.305 Procedures for handling ex parte communication

A decisional employee who receives or who makes or knowingly causes to be made a communication prohibited by § 16.303 shall place on the public record of the proceeding:

(a) All such written communications;

(b) Memoranda stating the substance of all such oral communications; and

(c) All written responses, and memoranda stating the substance of all oral responses, to the materials described in paragraphs (a) and (b) of this section.

§ 16.307 Requirement to show cause and imposition of sanction.

(a) Upon receipt of a communication knowingly made or knowingly caused to be made by a party in violation of § 16.303, the Administrator or his designee or the hearing officer may, to the extent consistent with the interests of justice and the policy of the underlying statutes, require the party to show cause why his or her claim or interest in the proceeding should not be dismissed, denied, disregarded, or otherwise adversely affected on account of such violation.

(b) The Administrator may, to the extent consistent with the interests of justice and the policy of the underlying statutes administered by the FAA, consider a violation of this subpart sufficient grounds for a decision adverse to a party who has knowingly committed such violation or knowingly caused such violation to occur.

Subpart J—Alternate Procedure for Certain Complaints Concerning Airport Rates and Charges

§ 16.401 Availability of alternate procedure.

(a) A scheduled air carrier holding a certificate of public convenience and necessity under 49 U.S.C. 1371, 1372, or 1388 or an exemption from those sections under 14 CFR part 298, may bring a complaint under this part using the procedures in this subpart.

(b) The procedures in this subpart are used only when all of the following requirements are met:

(1) The complaint alleges that an increase in the fee charged by an airport proprietor to scheduled air carriers is unreasonable within the meaning of 49 U.S.C. 1513 (a) through (d), or is unreasonable or unjustly discriminatory within the meaning of 49 U.S.C. 2210(c)(1);

(2) The Assistant Administrator, in his or her discretion, determines that the complaint involves a matter which, if not resolved by expedited procedure, may result in a substantial adverse impact on air transportation or that determines that the complaint involves a significant policy issue;

(3) The complaint meets the requirements for the filing of a complaint set forth in subparts B and C of this part; and

(4) The complaint includes an express request that the complaint be processed under this subpart.

(c) The Assistant Administrator may permit another air carrier eligible to file a complaint under paragraphs (a) and (b) of this section to join the complaint. A motion for joinder shall be filed on or before the date the answer is due to be filed.

(d) Other than joinder of additional parties under paragraph (c) of this section, participation in proceedings under this subpart by persons other than complainants will be permitted only through the filing of a written brief by a person with a substantial interest in the proceeding at the discretion of the presiding officer before issuance of the report of investigation, or by the Assistant Administrator after issuance of the report. A person may file a motion to submit a written brief to the presiding officer or the Assistant Administrator, as appropriate.

§ 16.403 Answer and other documents.

(a) Within seven calendar days of receiving a complainant requesting processing under this subpart, the Assistant Administrator serves on the complainant and each person named in the complaint the agency's determination whether the complaint—

(1) Meets the other requirements of this subpart; and

(2) Meets the requirements of subparts B and C of this part for the filing of complaints.

(b) If the Assistant Administrator determines that the complaint meets the requirements for a complaint under this subpart, each respondent shall file an answer within 21 days of service of the determination in paragraph (a) of this section.

(c) If the Assistant Administrator determines that the complaint does not meet the requirements of this subpart but does meet the requirements of subpart C of this part for the filing of a complaint, the complaint will be processed under § 16.29.

(d) The Assistant Administrator may dismiss a complaint as provided in §§ 16.25 and 16.27.

(e) The answer and all documents filed and served under this subpart shall be filed and served by personal delivery. All other requirements of subpart B of this part apply to the filing and service of documents under this subpart.

(f) The Assistant Administrator may for good cause grant an extension of the date by which the report of investigation is due.

§ 16.405 Notice and order of investigation.

Within seven days after the answer is served, the Assistant Administrator issues a notice and order of investigation. The investigation order states:

(a) The scope of the investigation, by describing the information sought in terms of its subject matter or its relevance to specified allegations;

(b) A description of the remedial or enforcement actions that may be ordered in the event that a rate or charge is found to be useful, including those provided in § 16.109(a).

(c) Such rules of procedure as may be necessary to supplement this part;

(d) The name and address of the presiding officer and the authority delegated to the presiding officer to conduct the investigation in accordance with the procedures set forth in this part;

(e) The date by which the presiding officer is directed to issue a report of investigation, normally 60 days after filing of the answer.

§ 16.407 Presiding officer.

(a) The presiding officer is a person designated by the Assistant Administrator who is neither an agency attorney, as defined in this part, nor a person otherwise engaged in the investigation of airport compliance.

(b) In accordance with the rules of this part, a presiding officer may:

(1) Give notice of, and hold, prehearing conferences and investigative hearings;

(2) Administer oaths and affirmations;

(3) Issue subpoenas authorized by law;

(4) Rule on offers of proof;

(5) Receive relevant and material evidence;

(6) Regulate the course of the hearing in accordance with the rules of this part to avoid unnecessary and duplicative proceedings in the interest of prompt and fair resolution of the matters at issue;

(7) Hold conferences to settle or to simplify the issues by consent of the parties;

(8) Dispose of procedural motions and requests; and

(9) Examine witnesses.

(c) The presiding officer shall issue a report of investigation which shall include findings of fact and, if directed by the Assistant Administrator, proposed conclusions of law.

§ 16.409 Parties.

(a) Parties may appear as provided in § 16.203(a) of this part.

(b) The parties to the investigation are the complainant(s), and the respondent(s).

(c) The FAA is represented by an agency attorney who, for the purposes of this part, will be deemed to be in the position of a party. The function of the agency attorney is to assist in development of a complete record for decision by the Assistant Administrator.

§ 16.411 Investigation procedure.

(a) *Investigative hearing.* The presiding officer shall hold an evidentiary hearing to investigate the factual matters identified in the investigative order. The hearing may be in person or, alternatively, by oral argument following submission of documentary evidence if the presiding officer determines that there are no genuine issues of material fact that require oral examination of witnesses and that documentary evidence in combination with oral argument is sufficient to develop a complete record. Oral proceedings will be transcribed and a transcript made available to the parties.

(b) *Discovery.* Discovery is limited to requests for admissions and requests for production of documents. The presiding officer may—

(1) Require parties to submit discovery requests to the presiding officer;

(2) Submit requests to the parties as modified by the presiding officer in the interest of relevance, economy, and completeness of the record for decision; and

(3) Require that responses be submitted to the presiding officer with service on other parties.

(c) *Witnesses.* Consistent with paragraph (a), witnesses may be designated and appear as provided in §§ 16.217 and 16.221(a). The presiding officer may exclude testimony as provided in § 16.221(b).

(d) *Subpoenas.* Where necessary to ensure a complete record, the presiding officer may issue a subpoena to compel a complainant or respondent, or an officer, employee, or agent of a complainant or respondent, to testify or to produce documents at the investigatory hearing. Issuance of, service of, and motions regarding subpoenas shall be in accordance with § 16.219.

(e) *Evidence.* A party may offer direct and rebuttal evidence in accordance with this section.

(1) *Requirement for written testimony and evidence.* Except in the case of evidence obtained by subpoena, a party's direct and rebuttal evidence, including testimony of witnesses, shall be submitted in written form, in advance of any oral hearing pursuant to the schedule established by the presiding officer. Written direct and rebuttal fact testimony shall be certified by the witness as true and correct. Oral examination of a party's own witness is limited to certification of the accuracy of written evidence, including correction and updating, if necessary, and redirect examination following cross-examination by other parties.

(2) *Cross-examination.* A party may conduct cross-examination needed for disclosure of the facts, subject to the control of the presiding officer for fairness, expedition, and exclusion of extraneous matters.

(3) *Admission of evidence.* The presiding officer admits evidence in accordance with this section, but may exclude irrelevant, immaterial, privileged, or unduly repetitious evidence.

(4) *Expert or opinion witnesses.* An employee of the FAA or DOT may not be called as an expert or opinion witness for any party other than the agency except as provided in Department of Transportation regulations at 49 CFR part 9.

(f) *Public disclosure of evidence.* Proceedings under this part are open to the public. Evidence is disclosed or withheld from public disclosure as provided in § 16.225. Objections to public disclosure may be filed with and ruled on by the presiding officer.

(g) *Location of hearing.* The investigative hearing shall be conducted at a place or places designated by the presiding officer with due regard for the convenience of the parties and the expeditious and efficient handling of the investigation.

(h) *Offer of proof.* A party whose evidence has been excluded by a ruling of the presiding officer may make an offer of the proof to be included in the record.

(i) *Exclusive record.* The pleadings, transcript of the hearing, all exhibits received into evidence, all motions, applications, requests and rulings, and all documents included in the hearing record shall constitute the exclusive record for the report of investigation.

(j) *Argument before the presiding officer.* During the hearing, the presiding officer shall give the parties reasonable opportunity to present oral argument on the record supporting or opposing motions, objections, and rulings. In addition, the presiding officer may permit oral argument on the merits of the case. The presiding officer may request the parties to submit proposed findings of fact and conclusions of law.

§ 16.413 Report of investigation.

(a) On or before the date set in the notice and order of investigation, the presiding officer shall issue a written report of investigation based on the record developed during the investigation. The report shall include a concise summary of the evidence and findings of fact and, if directed by the Assistant Administrator, conclusions of law, on the issues set forth in the order of investigation.

(b) The presiding officer shall transmit the report of investigation and the record to the Assistant Administrator.

(c) The presiding officer shall file the report of investigation in the Enforcement Docket and serve copies on the parties.

§ 16.415 Initial determination.

(a) Within 120 days after the complaint is filed, unless extended by the Assistant Administrator upon agreement of all the parties, the Assistant Administrator will render an initial determination and serve it on each party by certified mail, return receipt requested, or personal delivery.

(b) The initial determination will set forth a concise explanation of the factual and legal basis for the Assistant Administrator's determination on each claim made by the complainant.

(c) A party adversely affected by the initial determination may appeal the initial determination as provided in § 16.31(c) or 16.31(d).

§ 16.417 Eligibility for grants pending final agency decision.

(a) *Suspension of eligibility.* If the initial determination under § 16.415 is that the challenged increase in rates and charges is unreasonable or unjustly discriminatory, the respondent's eligibility to receive new Airport Improvement Program grants under the AAIA and to receive payments under existing grants is suspended effective 30 days after the issuance of the initial determination, unless the respondent files a notice of resolution of complaint or a notice of rescission under this section.

(b) *Rescission of increase.* The suspension of eligibility is deferred if, within 30 days after service of the initial determination, the respondent does one of the following—

(1) Rescinds the increase in rates or charges. To implement the rescission for purposes of this part, the respondent shall file a notice of rescission in the

Enforcement Docket and serve a copy on each party.

(2) Resolves the dispute through agreement with other parties, subject to the concurrence of the Assistant Administrator. The respondent shall indicate resolution by the filing of a joint motion for dismissal and for withdrawal of the complaint in the Enforcement Docket. In exercising discretion whether to grant the motion, the Assistant Administrator will consider, among other things, whether all parties have joined the motion and the effect of the proposed resolution on non-party aeronautical users of the airport.

(c) Deferral of the suspension of eligibility for grants and grant payments under this section does not limit the FAA's authority to impose any sanction or remedy for the past or continuing imposition of an unreasonable or unjustly discriminatory fee, including ordering refund with interest of fees paid prior to the effective date of the order.

(d) Notwithstanding the provision for suspension of eligibility in paragraph (a) of this section, the Assistant Administrator may execute a grant agreement or approve payment under an existing grant if necessary to correct or prevent an unsafe condition.

Issued in Washington, DC, on June 3, 1994

Federico Peña,

Secretary of Transportation.

David R. Hinson,

Administrator, Federal Aviation Administration.

[FR Doc. 94–13942 Filed 6–6–94; 12:42 pm]

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federal register

Thursday
June 9, 1994

Part IV

Department of Labor

Office of the Secretary

29 CFR Part 70
Freedom of Information Act; Technical Amendment; Final Rule

DEPARTMENT OF LABOR

Office of the Secretary

29 CFR Part 70

Freedom of Information Act; Technical Amendment

AGENCY: Office of the Secretary, Labor.

ACTION: Notice of final rulemaking; technical amendment.

SUMMARY: This document amends Appendix A to the Department of Labor's regulation relating to the Freedom of Information Act (FOIA). Appendix A lists the disclosure officers under FOIA. This amendment will delete one office, will update the name of another office, and will update the titles and the addresses within Appendix A so that the publication of the disclosure officers will be accurate. The document also adds an Appendix B which will list the names of the Department's FOIA/PA Coordinators.

EFFECTIVE DATE: June 9, 1994.

FOR FURTHER INFORMATION CONTACT: Miriam McD. Miller, Co-Counsel for Administrative Law, Office of the Solicitor, U.S. Department of Labor, room N–2428, 200 Constitution Avenue, NW., Washington, DC 20210, Telephone: (202) 219–8188.

SUPPLEMENTARY INFORMATION: This document amends Appendix A to the Department of Labor's regulation implementing the Freedom of Information Act (FOIA). Appendix A lists the disclosure officers under FOIA. This amendment will delete one office, will update the name of another office, and will update the titles and the addresses within Appendix A so that the publication of the disclosure officers will be accurate. The document also adds an Appendix B which will list the names of the Department's FOIA/PA Coordinators.

Publication in Final

The Department has determined that these amendments need not be published as a proposed rule, as generally required by the Administrative Procedure Act (5 U.S.C. 553)(APA) since this rulemaking merely reflects agency organization, procedure, or practice. It is thus exempt from notice and comment by virtue of section 553(b)(A).

Effective Date

This document will become effective upon publication pursuant to 5 U.S.C. 553(d). The undersigned has determined that good cause exists for waiving the customary requirement for delay in the effective date of a final rule for 30 days following its publication. This determination is based upon the fact that the rule is technical and nonsubstantive, and merely reflects agency organization, practice and procedure.

Executive Order 12866

This rule is not classified as a "rule" under Executive Order 12866 on federal regulations, because it is a regulation relating to agency organization, management or personnel. See section 3(d)(3) which exempts this rule.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this rule under section 553(b) of the APA, the requirements of the Regulatory Flexibility Act (5 U.S.C. 601) pertaining to regulatory flexibility analysis do not apply to this rule. See 5 U.S.C. 601(2).

Paperwork Reduction Act

This final rule is not subject to section 3504(h) of the Paperwork Reduction Act (44 U.S.C. 3501) since it does not contain any new collection of information requirements.

List of Subjects in 29 CFR Part 70

Freedom of information.

Accordingly, part 70 subtitle A of title 29 of the Code of Federal Regulations is amended as follows:

PART 70—EXAMINATION AND COPYING OF DEPARTMENT OF LABOR RECORDS

1. The authority citation for part 70 continues to read as follows:

Authority: 5 U.S.C. 301, 552, as amended by Pub. L. 93–502, 88 Stat. 1561; 29 U.S.C. 9(b); Reorganization Plan No. 6 of 1950; 64 Stat. 1263 5 U.S.C. Appendix

Appendix A to Part 70—Disclosure Officers [Amended]

2. Appendix A to part 70 is amended by removing paragraph (a)(7), by redesignating current paragraphs (a)(8) through (a)(20) as new paragraphs (a)(7) through (a)(19), and by revising the newly redesignated paragraph (a)(12) (which currently contains the Office of Labor-Management Standards) to read as follows:

(a) * * *

(12) Office of the American Workplace

* * * * *

PART 70—[AMENDED]

3. Part 70 is amended by revising paragraph (b) of Appendix A to Part 70—Disclosure Officers to read as follows:

* * * * *

(b)(1) The titles of the responsible officials of the various independent agencies in the Department of Labor are listed below. This list is provided for information and to assist requesters in locating the office most likely to have responsive records. The officials may be changed by appropriate designation. Unless otherwise specified, the mailing addresses of the officials shall be: U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Secretary of Labor, Attention: Assistant Secretary for Administration and Management (OASAM)
Deputy Solicitor, Office of the Solicitor
Chief Administrative Law Judge, Office of the Administrative Law Judges (OALJs)
Assistant Secretary for Administration and Management (OASAM)
Deputy Assistant Secretary for Administration and Management (OASAM)
Director, National Capital Service Center (NCSC)
Deputy Director, National Capital Service Center (NCSC)
Director, Office of Personnel Management Services (NCSC)
Director, Office of Procurement Services (NCSC)
Director, Directorate of Personnel Management (OASAM)
Deputy Director, Directorate of Personnel Management (OASAM)
Comptroller, Office of the Comptroller (OASAM)
Deputy Comptroller, Office of the Comptroller (OASAM)
Director, Office of Budget (Comptroller-OASAM)
Director, Office of Accounting (Comptroller-OASAM)
Director, Office of Financial Policy and Systems (Comptroller-OASAM)
Director, Directorate of Administrative and Procurement Programs (OASAM)
Director, Office of Facilities Management (OASAM)
Chief, Division of Security and Emergency Preparedness (OASAM)
Director, Office of Acquisition Integrity (OASAM)
Director, Office of Safety and Health (OASAM)
Director, Directorate of Civil Rights (OASAM)
Director, Directorate of Information Resources Management (DIRM-OASAM)
Director, Office of IRM Policy (DIRM-OASAM)
Director, DOL Academy
Director, Office of Small Business and Minority Affairs
Comptroller, Office of the Comptroller (OASAM)
Director, Office of Safety and Health (OASAM)
Director, Directorate of Civil Rights (OASAM)
Director, Office of Employee and Labor-Management Relations (OASAM)
Director, Office of Employment and Evaluation (OASAM)
Chief, Division of Security and Emergency Preparedness (OASAM)

Director, Office of Acquisition Integrity (OASAM)
Chairperson, Employees' Compensation Appeals Board (ECAB)
Deputy Assistant Secretary for Policy
Deputy Director, Office of Information and Public Affairs
Director, Office of Administrative Appeals
Assistant Inspector General, Office of Resource Management and Legislative Assessment, Office of the Inspector General (OIG)
Director, Office of Management, Administration and Planning, Bureau of International Labor Affairs (ILAB)
Assistant Secretary for the American Workplace (OAW)
Deputy Assistant Secretary for Labor-Management Programs, OAW
Deputy Assistant Secretary for Labor-Management Standards, OAW
Deputy Assistant Secretary for Work and Technology Policy, OAW
Commissioner, Bureau of Labor Statistics

The mailing address for responsible officials in the Bureau of Labor Statistics is: Rm. 4040—Postal Square Bldg., 2 Massachusetts Ave., NE., Washington, DC 20212–0001.

Assistant Secretary for Employment Standards, Employment Standards Administration (ESA)
Director, Office of Workers' Compensation Programs (OWCP), Assistant to the Director, OWCP, ESA
Director for Federal Employees' Compensation, OWCP, ESA
Director for Longshore and Harbor Workers' Compensation, OWCP, ESA
Director for Coal Mine Workers' Compensation, OWCP, ESA
Administrator, Wage and Hour Division, ESA
Deputy Administrator, Wage and Hour Division, ESA
Assistant Administrator, Office of Program Operations, Wage and Hour Division, ESA
Assistant Administrator, Office of Policy, Planning and Review, Wage and Hour Division, ESA
Deputy Assistant Administrator, Wage and Hour Division, ESA
Director, Office of Federal Contract Compliance Programs (OFCCP), ESA
Director, Division of Policy, Planning and Program Development, OFCCP, ESA
Director, Division of Program Operations, OFCCP, ESA
Director, Office of Management, Administration and Planning, ESA
Director, Division of Personnel and Organization Management, ESA
Director, Division of Internal Management Control, ESA
Director, Equal Employment Opportunity Unit, ESA
Director, Office of Public Affairs, ESA
Director, Division of Policy and Research Analysis, ESA
Assistant Secretary of Labor, Employment and Training Administration (ETA)
Deputy Assistant Secretary of Labor, Employment and Training Administration (ETA)
Administrator, Office of Financial and Administative Management, ETA
Director, Office of Management Support, ETA
Director, Office of Human Resources, ETA
Director, Office of the Comptroller, ETA
Director, Office of Information Resources Management, ETA
Director, Office of Grants and Contracts Management, ETA
Chief, Division of Acquisition and Assistance, ETA
Administrator, Office of Regional Management, ETA
Administrator, Office of Strategic Planning and Policy Development, ETA
Director, Unemployment Insurance Service, ETA
Director, United States Employment Service, ETA
Chief, Division of Foreign Labor Certifications, ETA
Administrator, Office of Job Training Programs, ETA
Director, Office of Employment and Training Programs, ETA
Director, Office of Job Corps, ETA
Director, Office of Special Targeted Programs, ETA
Administrator, Office of Work-Based Learning, ETA
Director, Bureau of Apprenticeship and Training, ETA
Director, Office of Worker Retraining and Adjustment Programs, ETA
Director, Office of Trade Adjustment Assistance, ETA
Director, Office of Equal Employment Opportunity Occupational Safety and Health Administration (OSHA)
Director, Office of Management Accountability and Performance, OSHA
Director, Office of Information and Consumer Affairs, OSHA
Director, Office of Field Operations, OSHA
Director, Office of Construction and Engineering, OSHA
Director, Directorate of Federal-State Operations, OSHA
Director, Directorate of Policy, OSHA
Director, Directorate of Administrative Programs, OSHA
Director, Office of Personnel Management, OSHA
Director, Office of Administrative Services, OSHA
Director, Office of Management Data Systems, OSHA
Director, Office of Management Systems and Organization, OSHA
Director, Office of Program Budgeting, Planning and Financial Management, OSHA
Director, Directorate of Technical Support, OSHA
Director, Directorate of Safety Standards Programs, OSHA
Director, Directorate of Health Standards Programs, OSHA
Director, Office of Statistics, OSHA
Director of Program Services, Pension and Welfare Benefits Administration
Assistant Secretary for Veterans' Employment and Training (VETS)
Deputy Assistant Secretary for Veterans' Employment and Training, VETS
Director, Office of Information, Management and Budget, VETS

The mailing address for responsible officials in the Mine Safety and Health Administration is: 4015 Wilson Boulevard, Arlington, Virginia 22203.

Deputy Assistant Secretary
Chief, Office of Congressional and Legislative Affairs
Director, Office of Information and Public Affairs
Administrator for Coal Mine Safety and Health
Chief, Office of Technical Compliance and Investigation (Coal)
Administrator for Metal and Nonmetal Mine Safety and Health
Director, Office of Assessments
Director, Office of Standards, Regulations and Variances
Director of Program Planning and Evaluation
Director of Administration and Management
Director of Educational Policy and Development

The mailing address for the Office of Administrative Law Judges and the Benefits Review Board is, respectively: 800 K Street, NW., Washington, DC 20001–8002 and 20001–8001.

Chief, Office of Administrative Law Judges, suite 400–N.
Chair, Benefits Review Board, suite 500–N.

(2) The titles of the responsible officials in the field offices of the various independent agencies are listed below: Unless otherwise specified, the mailing address for these officials by region, shall be:

Region I:

One Congress Street, 11th floor, Boston, Massachusetts 02114.

In Region I, Only, the Mailing Address For OSHA Is:

133 Portland Street, 1st floor, Boston, Massachusetts 02114.

Region II:

201 Varick Street, New York, New York 10014.

Region III:

Gateway Building, 3535 Market Street, Philadelphia, Pennsylvania 19104.

Region IV:

1375 Peachtree Street, NE., Atlanta, Georgia 30367.
214 N. Hogan Street, suite 1006, Jacksonville, Florida 32202, (OWCP Only).

Region V:

Kluczynski Federal Building, 230 South Dearborn Street, Chicago, Illinois 60604.
1240 East Ninth Street, room 851, Cleveland, Ohio 44199, (FEC only).

Region VI:

525 Griffin Square Building, Griffin & Young Streets, Dallas, Texas 75202.

Region VII:

Federal Office Building, 911 Walnut Street, Kansas City, Missouri 64106.

Region VIII:

Federal Office Building, 1961 Stout Street, Denver, Colorado 80294.
and
1801 California Street, Denver, Colorado 80202.

The mailing address for the Director of the Regional Bureau of Apprentice and Training in Region VIII is:

Room 465, U.S. Custom House, 721—19th Street, Denver, CO. 80202.

Region IX:

71 Stevenson Street, San Francisco, California 94105.

Region X:

111 Third Avenue, Seattle, Washington 98101–3212.
Regional Administrator for Administration and Management (OASAM)
Regional Personnel Officer, OASAM
Regional Director for Information and Public Affairs
Regional Administrator for Employment and Training Administration (ETA)
Regional Director, Job Corps, ETA
Director, Regional Bureau of Apprenticeship and Training, ETA
Regional Management Analyst, ETA-Atlanta, Georgia
Regional Administrator for Wage and Hour, ESA
Regional Director for Federal Contract Compliance Programs, ESA
Regional Director for the Office of Workers' Compensation Programs, ESA
District Director, Office of Workers' Compensation Programs, ESA

Wage and Hour Division, ESA Responsible Officials, District Offices

135 High Street, room 310, Hartford, Connecticut 06103.
66 Pearl Street, room 211, Portland, Maine 04101.
One Bowdoin Square, 8th floor, Boston, Massachusetts 02114.
200 Sheffield St., room 102, Mountainside, New Jersey 07092.
3131 Princeton Pike, Building 5, room 216, Lawrenceville, New Jersey 08648.
Leo W. O' Brien Federal Bldg. rm. 822, Albany, New York 12207.
1967 Turnbull Avenue, Bronx, New York 10473.
111 West Huron Street, room 617, Buffalo, New York 14202.
825 East Gate Boulevard, room 202, Garden City, New York 11530.
26 Federal Plaza, room 3838, New York, New York 10278.
159 Carlos Chardon Street, room 102, Hato Rey, Puerto Rico 00918.
Federal Office Building, room 913, 31 Hopkins Plaza, Charles Center, Baltimore, Maryland 21201.
U.S. Custom House, room 238, Second and Chestnut Streets, Philadelphia, Pennsylvania 19106.
Federal Building, room 313, 1000 Liberty Avenue, Pittsburgh, Pennsylvania 15222.
3329 Penn Place, 20 North Pennsylvania Ave., Wilkes-Barre, Pennsylvania 18701.
Federal Building, room 7000, 400 North Eighth Street, Richmond, Virginia 23240.
2 Hale Street, suite 301, Charleston, West Virginia 25301–2834.
1375 Peachtree St NE., room 668, Atlanta, Georgia 30367.
Berry Building, suite 301, 2015 North Second Avenue, Birmingham, Alabama 35203.
Federal Building, room 407, 299 East Broward Boulevard, Fort Lauderdale, Florida 33301.
3728 Phillips Hwy., suite 219, Jacksonville, Florida 32207.
1150 Southwest First Street, room 202, Miami, Florida 33130.
Austin Laurel Bldg., suite 300, 4905 W. Laurel Street, Tampa, Florida 33607.
Federal Building, room 167, 600 Martin Luther King Jr. Place, Louisville, Kentucky 40202.
800 Briar Creek Road, suite CC–412, Charlotte, North Carolina 28205.
Somerset Park Building, 4407 Bland Rd., suite 260, Raleigh, North Carolina 27609.
Federal Building, room 1072, 1835 Assembly Street, Columbia, South Carolina 29201.
1 Jackson Place, No.1020, 188 East Capitol Street, Jackson, Mississippi 39210.
1321 Murfreesboro Road, suite 511, Nashville, Tennessee 37217.
230 South Dearborn Street, room 412, Chicago, Illinois 60604–1595.
509 West Capitol Avenue, suite 205, Springfield, Illinois 62704.
46 East Ohio Street, room 148, Indianapolis, Indiana 46204–1919.
River Glen Plaza, suite 160, 501 East Monroe, South Bend, Indiana 46601–1615.
2920 Fuller Avenue, NE., suite 100, Grand Rapids, Michigan 49505–3409.
Bridge Place, room 106, 220 South Second Street, Minneapolis, Minnesota 55401–2104.
Federal Office Building, room 817, 1240 East Ninth Street, Cleveland, Ohio 44199–2054.
525 Vine Street, room 880, Cincinnati, Ohio 45202–3268.
646 Federal Office Building, 200 North High Street, Columbus, Ohio 43215–2475.
Federal Center Building, room 309, 212 East Washington Avenue, Madison, Wisconsin 53703–2878.
Savers Building, suite 611, 320 West Capitol, Little Rock, Arkansas 72201.
701 Loyola Avenue, room 13028, New Orleans, Louisiana 70113.
Western Bank Bldg., suite 840, 505 Marquette, NW., Albuquerque, New Mexico 87102–2160.
Government Plaza Building, room 307, 400 Mann Street, Corpus Christi, Texas 78401.
Federal Building, room 507, 525 South Griffin Street, Dallas, Texas 75202.
2320 LaBranch, room 2100, Houston, Texas 77004.
Northchase I Office Building, suite 140, 10127 Morocco, suite 104, San Antonio, Texas 78216.
Fifty-One Yale Building, suite 303, 5110 South Square, Tulsa, Oklahoma 74135–7438.
Federal Building, room 643, 210 Walnut Street, Des Moines, Iowa 50309.
Federal Office Building, room 2900, 911 Walnut Street, Kansas City, Missouri 64106.
1222 Spruce Street, rm. 9102B, St. Louis, Missouri 63103.
Federal Building, room 715, 106 South 15th Street, Omaha, Nebraska 68102.
Room 615, Federal Office Building, 1961 Stout Street, PO Drawer 3505, Denver, Colorado 80294.
10 West Broadway, suite 307, Salt Lake City, Utah 84101.
3221 North 16th Street, suite 301, Phoenix, Arizona 85016.
300 South Glendale Avenue, room 250, Glendale, California 91205–1752.
2981 Fulton Avenue, Sacramento, California 95821.
211 Main Street, room 341, San Francisco California 94105.
5675 Ruffin Road, suite 320, San Diego, California 92123–5378.
111 SW Columbia, suite 1010, Portland, Oregon 97201–5842.
1111 Third Avenue, suite 755, Seattle, Washington 98101–3212.

Office of Federal Contract Compliance Programs, ESA, Responsible Officials, Regional Offices

One Congress Street, 11th floor, Boston, Massachusetts 02114.
201 Varick Street, room 750, New York, New York 10014.
Gateway Building, room 15340, 3535 Market Street, Philadelphia, Pennsylvania 19104.
1375 Peachtree Street, NE., suite 678, Atlanta, Georgia 30367.
Kluczynski Federal Building, room 570, 230 South Dearborn Street, Chicago, Illinois 60604.
Federal Building, room 840, 525 South Griffin Street, Dallas, Texas 75202.
Federal Office Building, 911 Walnut Street, room 2011, Kansas City, Missouri 64106.
1801 California Street, suite 935, Denver, Colorado 80202.
71 Stevenson Street, suite 1700, San Francisco, California 94105.
1111 Third Avenue, suite 610, Seattle, Washington 98101–3212.

Office of Workers' Compensation Programs, ESA, Responsible Officials, District Directors

One Congress Street, 11th Floor, Boston, Massachusetts 02203, (FECA and LHWCA only).
201 Varick Street, Seventh Floor, New York, New York 10014, (FECA and LHWCA only).
3535 Market Street, Philadelphia, Pennsylvania 19104, (FECA and LHWCA only).
Penn Traffic Building, 319 Washington Street, Johnstown, Pennsylvania 15901, (BLBA only).
South Main Towers, 116 South Main Street, room 208, Wilkes-Barre, Pennsylvania 18701, (BLBA only).
Wellington Square, 1225 South Main Street, Greensburg, Pennsylvania 15601, (BLBA only).
31 Hopkins Plaza, room 1026, Baltimore, Maryland 22201, (LHWCA only).
Federal Building, 200 Granby Mall, room 212, Norfolk, Virginia 23510, (LHWCA only).
2 Hale Street, suite 304, Charleston, West Virginia 25301, (BLBA only).
609 Market Street, Parkersburg, West Virginia 26101, (BLBA only).
800 North Capitol Street, NW., Washington, DC 20211, (FECA only).
1200 Upshur Street, NW., Washington, DC 20210, (DCCA only).
334 Main Street, Fifth Floor, Pikeville, Kentucky 41501, (BLBA only).
500 Springdale Plaza, Spring Street, Mt. Sterling, Kentucky 40353, (BLBA only).

214 N. Hogan Street, 10th Floor, Jacksonville, Florida 32201, (FECA and LHWCA only).
230 South Dearborn Street, 8th floor, Chicago, Illinois 60604, (FECA and LHWCA).
1240 East 9th Street, Cleveland, Ohio 44199, (FECA only).
274 Marconi Boulevard, 3rd Floor, Columbus, Ohio 43215, (BLBA only).
525 Griffin Street, Federal Building, Dallas, Texas 75202, (FECA only).
701 Loyola Avenue, room 13032, New Orleans, Louisiana 70113, (LHWCA only).
12600 North Featherwood Drive, Houston, Texas 77034, (LHWCA only).
911 Walnut Street, Kansas City, Missouri 64106, (FECA only).
1801 California Street, Denver, Colorado 80202, (FECA and BLBA only).
71 Stevenson Street, 2nd Floor, San Francisco, California 94105, (FECA and LHWCA only).
401 E. Ocean Boulevard, suite 720, Long Beach, California 90802, (LHWCA only).
300 Ala Moana Boulevard, room 5108, Honolulu, Hawaii 96850, (LHWCA only).
1111 3rd Avenue, Seattle, Washington 98101–3212, (LHWCA and FECA only).

Mine Safety & Health Administration Field Offices

Chief, Division of Mining Information System MSHA

P.O. Box 25367, DFC, Denver, CO 80225–0367.

Superintendent, National Mine Health and Safety Academy

P.O. Box 1166, Beckley, WV 25802–1166.

Chief, Approval and Certification Center, MSHA

R.R. Box 251, Industrial Park Road, Triadelphia, WV 26059.

District Manager for Coal Mine Safety and Health

Penn Place, room 3128, 20 N. Pennsylvania Avenue, Wilkes-Barre, PA 18701.
RR1, Box 736, Hunker, PA 15639.
5012 Mountaineer Mall, Morgantown, WV 26505.
100 Bluestone Road, Mt. Hope, WV 25880.
P.O. Box 560, Norton, VA 24273.
219 Ratliff Creek Road, Pikeville, KY 41501.
HC 66, Box 1762, Barbourville, KY 40906.
P.O. Box 418, Vincennes, IN 47591.
P.O. Box 25367, Denver, CO 80225–0367.
100 YMCA Drive, Madisonville, KY 42431–9019.

District Manager for Metal and NonMetal Mine Safety and Health

230 Executive Drive, Mars, PA 16046–9812.
135 Gemini Circle, suite 212, Birmingham, AL 35209.
515 W. 1st Street, #228, Duluth, MN 55802–1302.
1100 Commerce Street, room 4C50, Dallas, TX 75242–0499.
P.O. Box 25367, Denver, CO 80225–0367
3333 Vaca Valley Parkway, suite 600, Vacaville, CA 95688.

Office of Labor-Management Standards, Regional Directors—District Directors

OLMS Regional Directors

Suite 600, 1365 Peachtree Street, NE., Atlanta, GA 30367.
Suite 302, 121 High Street, Boston, MA 02110.
Suite 774, Federal Office Building, 230 S. Dearborn Street, Chicago, IL 60604.
Suite 831, Federal Office Building, 1240 E. Ninth Street, Cleveland, OH 44199.
Suite 300, 525 Griffin Sq. Bldg., Griffin & Young Streets, Dallas, TX 75202.
Suite 2200, Federal Office Bldg., 911 Walnut Street, Kansas City, MO 64106.
Suite 878, 201 Varick Street, New York, NY 10014.
Suite 9452, William Green Federal Bldg., 600 Arch Street, Philadelphia, PA 19106.
Suite 725, 71 Stevenson Place, San Francisco, CA 94105.
Suite 558, Riddell Bldg., 1730 K Street, NW., Washington, DC 20006.

OLMS District Directors

Suite 1310, Federal Bldg., 111 W. Huron Street, Buffalo, NY 14202.
Suite 950, 525 Vine Street, Cincinnati, OH 45202.
Suite 940, 1801 California Street, Denver, CO 80202–2614.
Suite 630, Federal Bldg., & Courthouse, 231 W. Lafayette Street, Detroit, MI 48226.
Suite 350, Federal Office Bldg., Carlos Chardon Street, Hato Rey, PR 00918.
Suite 165, 401 Louisiana Street, Houston, TX 77002.
Suite 708, 3660 Wilshire Boulevard, Los Angeles, CA 90010.
Suite 503, Washington Square Bldg., 111 NW 183rd Street, Miami, FL 33169.
Suite 118, 517 East Wisconsin Avenue, Milwaukee, WI 53202–4504.
Suite 100, Bridgeplace, 220 South Second Street, Minneapolis, MN 55401.
Suite 238, 233 Cumberland Bend Drive, Nashville, TN 37228.
Metro Star Plaza, 190 Middlesex/Essex Turnpike, Iselin, NJ 08830.
Suite 804, 234 Church Street, New Haven, CT 06510.
Suite 13009, 701 Loyola Avenue, New Orleans, LA 70113.
Suite 801, Federal Office Bldg., 1000 Liberty Avenue, Pittsburgh, PA 15222.
Suite 9109 E, 1222 Spruce Street, St. Louis, MO 63103.
Suite 880, 111 3rd Avenue, Seattle, WA 98101–3212.
Suite 301, 4905 W. Laurel Street, Tampa, FL 33607.

Regional Administrator, Occupational Safety and Health Administration (OSHA)

Area Director, OSHA

Valley Office Park, 13 Branch Street, Methuen, Massachusetts 01844.
639 Granite Street, 4th Floor, Braintree, Massachusetts 02184.
279 Pleasant Street, suite 201, Concord, New Hampshire 03301.
380 Westminister Mall, room 243, Providence, Rhode Island 02903.
1145 Main Street, room 108, Springfield, Massachusetts 01103–1493.
40 Western Avenue, room 121, Augusta, Maine 04330.
Federal Office Building, 450 Main Street, room 508, Hartford, Connecticut 06103.
One LaFayette Square, suite 202, Bridgeport, Connecticut 06604.
90 Church Street, room 1407, New York, New York 10007.
990 Westbury Road, Westbury, New York 11590.
42–40 Bell Boulevard, Bayside, New York 11361.
3300 Vikery Road, North New, Syracuse, New York 13212.
5360 Genesee Street, Bowmansville, New York 14026.
U.S. Courthouse & Federal Office Building, Carlos Chardon Avenue, room 559, Hato Key, Puerto Rico 00918.
401 New Karner Road, suite 300, Albany, New York 12205–3809.
Marlton Executive Park, Building 2, suite 120, 701 Route 73 South, Marlton, New Jersey 08053.
299 Cherry Hill Road, suite 304, Parsippany, New Jersey 07054.
500 Route 17 South, 2nd Floor, Hasbrouck Heights, New Jersey 07604.
Plaza 35, suite 205, 1030 St. Georges Avenue, Avenel, New Jersey 07001.
660 White Plains Road, 4th Floor, Tarrytown, New York 10591–5107.
US Custom House, room 242, Second & Chestnut Street, Philadelphia, Pennsylvania 19106.
One Rodney Square, suite 402, 920 King Street, Wilmington, Delaware 19801.
Federal Building, room 1428, 1000 Liberty Avenue, Pittsburgh, Pennsylvania 15222.
20 North Pennsylvania Avenue, Penn Place, room 2005, Wilkes-Barre, Pennsylvania 18701–3590.
850 North 5th Street, Allentown, Pennsylvania 18102.
550 Eagan Street, room 206, Charleston, West Virginia 25301.
3939 West Ridge Road, suite B12, Erie, Pennsylvania 16506–1857.
Progress Plaza, 49 North Progress Street, Harrisburg, Pennsylvania 17109.
Federal Building, room 1110, Charles Center, 31 Hopkins Plaza, Baltimore, Maryland 21201.
Federal Office Building, 200 Granby Street, room 835, Norfolk, Virginia 23510–1811.
La Vista Perimeter Office Park, Building 7, suite 110, Tucker, Georgia 30084.
2400 Herodian Way, suite 250, Smyrna, Georgia 30080.
450 Mall Boulevard, suite J, Savannah, Georgia 31406.
Todd Mall, 2047 Canyon Road, Birmingham, Alabama 35216.
3737 Government Boulevard, suite 100, Mobile, Alabama 36693.
1835 Assembly Street, room 1468, Columbia, South Carolina 29201.
Jacaranda Executive Court, 8040 Peters Road, Building H–100, Fort Lauderdale, Florida 33324.
3780 I–55 North, suite 210, Jackson, Mississippi 39211–6323.
3100 University Boulevard South, room 303, Jacksonville, Florida 32216
John C. Watts Federal Building, 330 West Broadway, room 108, Frankfort, Kentucky 40601.

2002 Richard Jones Road, suite C–205, Nashville, Tennessee 37215.
Century Station, 300 Fayetteville Mall, room 438, Raleigh, North Carolina 27601.
5807 Breckenridge Parkway, suite A, Tampa, Florida 33610.
1600 167th Street, suite 12, Calumet City, Illinois 60409.
O'Hara Lake Plaza, 2360 East Devon Avenue, suite 1010, Des Plaines, Illinois 60018.
344 Smoke Tree Business Park, North Aurora, Illinois 60542.
Federal Office Building, 1240 East 9th Street, room 899, Cleveland, Ohio 44199.
Federal Office Building, 200 N. High Street, room 620, Columbus, Ohio 43215.
US P.O. & Courthouse Building, 46 East Ohio Street, room 423, Indianapolis, Indiana 46204.
36 Triangle Park Drive, Cincinnati, Ohio 45246.
2618 North Ballard Road, Appleton, Wisconsin 54915.
Henry S. Reuss Building, room 1180, 310 West Wisconsin Avenue, Milwaukee, Wisconsin 53203.
110 South 4th Street, room 116, Minneapolis, Minnesota 55401.
234 North Summit Street, room 734, Toledo, Ohio 43604.
801 South Waverly Road, suite 306, Lansing, Michigan 48917–4200.
4802 East Broadway, Madison, Wisconsin 53716.
2918 W. Willow Knolls Road, Peoria, Illinois 61614.
8344 East R.L. Thornton Freeway, suite 420, Dallas, Texas 75228.
611 East 6th Street, Grant Building, room 303, Austin, Texas 78701.
Westbank Building, suite 820, 505 Marquette Avenue, NW., Albuquerque, New Mexico 87102.
2156 Wooddale Boulevard, Hoover Annex, suite 200, Baton Rouge, Louisiana 70806.
Government Plaza, 400 Mann Street, room 300, Corpus Christi, Texas 78401.
Federal Office Building, 1205 Texas Avenue, room 422, Lubbock, Texas 79401.
350 North Sam Houston Parkway East, room 120, Houston, Texas 77060.
17625 El Camino Real, suite 400, Houston, Texas 77058.
420 West Main Place, suite 300, Oklahoma City, Oklahoma 73102.
North Starr II, suite 430, 8713 Airport Freeway, Fort Worth, Texas 76180–7604.
Savers Building, suite 828, 320 West Capitol Avenue, Little Rock, Arkansas 72201.
4171 North Mesa Street, room C119, El Paso, Texas 79902.
6200 Connecticut Avenue, suite 100, Kansas City, Missouri 64120.
911 Washington Avenue, room 420, St. Louis, Missouri 63101.
210 Walnut Street, room 815, Des Moines, Iowa 50309.
300 Epic Center, 301 North Main, Wichita, Kansas 67202.
Overland—Wolf Building, room 100, 6910 Pacific Street, Omaha, Nebraska 68106.
5799 Broadmoor, suite 338, Mission, Kansas 66202.
19 North 25th Street, Billings, Montana 59101.
220 E. Rosser, room 348, P.O. Box 2439, Bismarck, North Dakota 58501.
7935 East Prentice Avenue, suite 209, Englewood, Colorado 80011–2714.
1391 Speer Boulevard, suite 210, Denver, Colorado 80204.
1781 South 300 West, PO Box 65200, Salt Lake City, Utah 84165–0200.
71 Stevenson Street, room 415, San Francisco, California 94105.
300 Ala Moana Boulevard, suite 5122, PO Box 50072, Honolulu, Hawaii 96850.
3221 North 16th Street, suite 100, Phoenix, Arizona 85016.
1050 East William, suite 435, Carson City, Nevada 89701.
301 West Northern Lights Boulevard, suite 407, Anchorage, Alaska 99503.
3050 North Lakeharbor Lane, suite 134, Boise, Idaho 83703.
121 107th Avenue, Northeast, room 110, Bellevue, Washington 98004.
1220 Southwest Third Avenue, room 640, Portland, Oregon 97204.

Pension and Welfare Benefits Administration Area Director or District Supervisor

Area Director, One Bowdoin Square, 7th Floor, Boston, Massachusetts 02114.
Area Director, 1633 Broadway, rm. 226, New York, NY 10019.
Area Director, 3535 Market Street, room M300, Gateway Building, Philadelphia, Pennsylvania 19104.
District Supervisor, 1730 K Street NW., suite 556, Washington, DC 20006.
Area Director, 1371 Peachtree Street NE., room 205, Atlanta, Georgia 30367.
District Supervisor, 111 NW. 183rd Street, suite 504, Miami, Florida 33169.
Area Director, 1885 Dixie Highway, suite 210, Ft. Wright, Kentucky 41011.
District Supervisor, 231 W. Lafayette Street, room 619, Detroit, Michigan 48226.
Area Director, 401 South State St., suite 840, Chicago, Illinois 60605.
Area Director, room 1700, 911 Walnut Street, Kansas City, Missouri 64106.
District Supervisor, 815 Olive Street, room 338, St. Louis, Missouri 63101.
Area Director, 525 Griffin Street, room 707 Dallas, Texas 75202.
Area Director, 71 Stevenson Street, suite 915, P.O. Box 190250, San Francisco, California 94119–0250.
District Director, 1111 Third Avenue, room 860, Seattle, Washington 98101–3212.
Area Director, 3660 Wilshire Boulevard, room 718, Los Angeles, California 90010.
Area Director, suite 514, 790 E. Colorado Blvd., Pasadena, CA 91101.

Regional Administrators, Veterans' Employment and Training Service (VETS)

Region I: One Congress Street, 11th Floor, Boston, Massachusetts 02114.
Region II: 201 Varick Street, room 766, New York, New York 10014.
Region III: U.S. Customs House, room 305, Second and Chestnut Streets, Philadelphia, Pennsylvania 19106.
Region IV: 1371 Peachtree Street, NE., room 326, Atlanta, Georgia 30367.
Region V: 230 South Dearborn, room 1064, Chicago, Illinois 60604.
Region VI: 525 Griffin Street, room 205, Dallas, Texas 75202.
Region VII: Federal Building, room 803, 911 Walnut Street, Kansas City, Missouri 64106.
Region VIII: 1801 California Street, suite 910, Denver, Colorado 80202–2614.
Region IX: 71 Stevenson Street, suite 705, San Francisco, California 94105.
Region X: 1111 Third Avenue, suite 800, Seattle, Washington 98101–3212.

PART 70—[AMENDED]

4. Part 70 is amended by adding an Appendix B to read as follows:

Appendix B to Part 70—Freedom of Information/Privacy Act Coordinators

The Departmental Legal and Administrative Contact is Miriam McD. Miller, Esq., Office of the Solicitor, Room N–2428, FPB, tel. (202) 219–8188; FAX (202) 219–6896. For direct assistance, you may wish to contact the following agency coordinators for the Freedom of Information Act and the Privacy Act:

Agency	Person	Address	Telephone [1]
Office of the Secretary (O/SECY)	Tena Lumpkins	Rm. N–1301, FPB	219–5095
Office of the Assistant Secretary for Admin. and Management (OASAM).	Tena Lumpkins	Rm. N–1301, FPB	219–5095
Office of the Admin. Law Judges (OALJ)	Mary Grace Dorsey	Suite 400–N, 800 K St., NW WDC	633–0355
Benefits Review Board (BRB)	Sharon Ratliff	Suite 500–N, 800 K St., NW WDC	633–7503
Office of the American Workplace, Ofc of Statutory Programs (OAW/OSP).	Kelly Andrews	RM. N–5411, FPB	219–4473
Bureau of Labor Statistics (BLS)	K. Kurz or D. Solis	Rm. 3255, PSB	606–7628
Employees Compensation Appeals Board (ECAB)	Mary Ellen McKenna	Rm. 300, Reporters Bldg.	401–6600

Agency	Person	Address	Telephone [1]
Employment Standards Admin. (ESA)	Dorothy Chester	Rm. S–3013C, FPB	219–8447
Employment and Training Admin. (ETA)	Patsy Files	Rm. N–4671, FPB	219–6695
Ofc of the Inspector General (OIG)	Pamela Davis	Rm. S–5506, FPB	219–6747
Deputy Under Secretary for International Labor Affairs (ILAB).	Patricia Clark	Rm. S–5303, FPB	219–6136
Office of Labor-Management Standards (OLMS)	James Santelli	Rm. N–5613, FPB	219–7373
Mine Safety and Health Admin. (MSHA)	Tom Brown	Rm. 605, BT#3 Arlington, VA	(703) 235–1452
Occupational Safety and Health Admin. (OSHA)	James Foster	Rm. N–3647, FPB	219–8148
Pension and Welfare Benefits Admin. (PWBA)	June Patron	Rm. N–5625, FPB	219–6999
President's Committee on the Employment of Persons with Disabilities (PCEPD).	Gregory Best	Suite 300, 1331 F St., NW WDC	376–6200
Office of the Solicitor (OSOL)	Elizabeth Newton	Rm. N–2414, FPB	219–6884
Veterans' Employment and Training Service (VETS)	Bernard Wroble	Rm. S–1310, FPB	219–6350

[1] All numbers are within area code (202) except MSHA.

Building Addresses

a. Frances Perkins Building, 200 Constitution Avenue, NW., Washington, DC 20210.

b. Postal Square Building, 2 Massachusetts Avenue, NE., Washington, DC 20212–0001.

c. Ballston Towers No. 3, 4015 Wilson Boulevard, Arlington, VA 22203.

d. Reporters' Building, 300 7th Street, SW., Washington, DC 20024.

e. Tech World, 800 K Street, NW., Washington, DC 20001–8002.

Signed at Washington, DC, this 1st day of June, 1994.

Robert B. Reich,

Secretary of Labor.

[FR Doc. 94–13882 Filed 6–8–94; 8:45 am]

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federal register

Thursday
June 9, 1994

Part V

Department of Health and Human Services

Substance Abuse and Mental Health Services Administration

Mandatory Guidelines for Federal Workplace Drug Testing Programs; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Mandatory Guidelines for Federal Workplace Drug Testing Programs

AGENCY: Substance Abuse and Mental Health Services Administration, PHS, HHS.

ACTION: Revised mandatory guidelines.

SUMMARY: The Department of Health and Human Services (HHS) revises some of the scientific and technical guidelines for Federal drug testing programs and revises certain standards for certification of laboratories engaged in urine drug testing for Federal agencies.

EFFECTIVE DATE: September 1, 1994.

FOR FURTHER INFORMATION CONTACT: Dr. Donna M. Bush, Chief, Drug Testing Section, Division of Workplace Programs, Substance Abuse and Mental Health Services Administration (SAMHSA), room 9A–53, 5600 Fishers Lane, Rockville, Maryland 20857, tel. (301) 443–6014.

SUPPLEMENTARY INFORMATION: The Department is revising the guidelines entitled "Mandatory Guidelines for Federal Workplace Drug Testing Programs," (Mandatory Guidelines) which were initially published in the **Federal Register** on April 11, 1988 (53 FR 11979). These Mandatory Guidelines and the revisions are developed in accordance with Executive Order No. 12564 dated September 15, 1986, and section 503 of Public Law 100–71, 5 U.S.C. section 7301 note, the Supplemental Appropriations Act for fiscal year 1987 dated July 11, 1987. The revisions to the Mandatory Guidelines incorporate changes based on the comments submitted and the Department's first 5 years of experience in implementing and administering these Guidelines.

BACKGROUND AND SUMMARY OF PUBLIC COMMENTS AND POLICIES OF THE REVISED GUIDELINES

A. Proposed Revised Mandatory Guidelines

The basic purpose of the Mandatory Guidelines is to establish scientific and technical guidelines for Federal agencies' workplace drug testing programs and to establish a certification program for laboratories engaged in urine drug testing for Federal agencies. The proposed revisions published in the **Federal Register** on January 25, 1993 (58 FR 6062), retained the basic requirements in the Mandatory Guidelines published in the **Federal Register** on April 11, 1988, but as indicated above refined some requirements in order to incorporate changes based on the Department's first 5 years of experience in implementing and administering these Guidelines.

The major changes proposed in the notice published in the **Federal Register** on January 25, 1993, are summarized here to facilitate the discussion of the comments received during the public comment period.

The Department proposed reducing the requirement to collect 60 mL of urine at the collection site to 30 mL. This change was proposed because many times donors have difficulty in providing the 60 mL of urine. In addition, 30 mL is adequate to complete the required testing and satisfy other program requirements.

The Department proposed to revise the specimen collection procedure to allow Federal agencies to use an optional "split specimen" collection procedure. Several Federal agencies have been granted waivers to use split specimen collection procedures during the past 5 years. Establishing a "split specimen" procedure will ensure that each Federal agency will be using the same procedure. The Department believes that appropriate guidance must be provided regarding the minimum acceptable volumes for the split specimens, measuring temperature before a single donor specimen is transferred into two separate specimen bottles, sending both split specimen bottles to the laboratory at the same time to ensure that they are subject to the same shipping and storage conditions, and specifying the procedures for testing Bottle B when the Bottle A specimen is reported positive.

The Department proposed to revise the collection procedure to allow Federal agencies to use an individual of the same gender, other than a collection site employee, to observe the collection of a specimen whenever there is reason to believe the individual may have altered or substituted the specimen. This change is based on the understanding that it is not always possible to have a collection site employee of the same gender observe the collection.

The Department proposed a change to allow a laboratory to use a certifying scientist who is only certified to review initial drug tests which are negative. This could assist in reducing the cost of testing without compromising the reliability of drug testing.

The Department proposed that the initial test level for marijuana metabolites be reduced from 100 ng/mL to 50 ng/mL. This change reflects advances in technology of immunoassay tests for marijuana metabolites.

The Department proposed to allow laboratories to use multiple immunoassay tests for the same drug or drug class. This would allow laboratories to use an initial test and then forward all presumptive positives for a second test by a different immunoassay technique to minimize possible presumptive positives due to the presence of structural analogues in the specimen. In addition, this policy would allow a laboratory to use a different immunoassay for specimens that may be untestable with one immunoassay.

The Department proposed that in order to report a specimen positive for only methamphetamine, the specimen must also contain the metabolite amphetamine at a concentration equal to or greater than 200 ng/mL by the confirmatory test. This proposed requirement would ensure that high concentrations of sympathomimetic amines available in over-the-counter and prescription medications will not be misidentified as methamphetamine.

The Department proposed reducing the number of blind samples a Federal agency must submit each quarter to its contracting laboratory from 10% of all samples to a minimum of 3% (with a maximum of 100 blind samples). This proposed change may significantly reduce the costs associated with maintaining a blind sample program without affecting the Federal agency's ability to monitor a laboratory's performance.

The performance testing sample portion of the laboratory certification program was proposed to be changed by reducing the performance testing (PT) challenges for certified laboratories from 6 cycles per year to 4 cycles per year. Experience in this and other performance testing programs indicates that 4 cycles per year is sufficient to assess a laboratory's ability to test and report results for performance testing samples.

The Department proposed restricting the types of arrangements that can exist between the Medical Review Officer (MRO) and the laboratory to ensure that a conflict of interest does not exist. The restrictions would require that the agency's MRO not be an employee or an agent of, or have any financial interest in, the laboratory for which the MRO is reviewing drug testing results. Similarly, the laboratory would be prohibited from entering into any agreement with an MRO that could be construed as a conflict of interest.

A new subpart D was proposed which provides detailed procedures for the

internal review of a suspension or proposed revocation of a laboratory's certification to perform drug testing. These procedures will ensure and provide a timely and fair review of all suspensions or proposed revocations.

The Department proposed that the written notice of the suspension which is sent to the laboratory, as well as the reviewing official's written decision upholding or denying suspension or proposed revocation under the review procedures in subpart D, would be made available to the public upon request. This provision ensures that the public has access to the documents containing the basis for HHS's actions.

B. Public Comments and the Department's Responses

The Department received 73 public comments on the proposed changes from Federal agencies, individuals, organizations, and companies. About 50% of these supported all or some of the proposed changes. All written comments were reviewed and taken into consideration in the preparation of the revised Mandatory Guidelines. The substantive concerns raised in the public comments and the Department's responses to the comments are set out below. Similar comments are considered together.

1. Definitions

A number of commenters expressed concerns with the definitions in section 1.2. It was suggested that the definition for chain of custody indicate that couriers do not need to document chain of custody while the specimens are in transit to the laboratory. The Department agrees that the Mandatory Guidelines should be clarified to address that issue. Specimens are sealed in packages and any tampering with a sealed specimen would be noticed by the laboratory and documented on the specimen chain of custody. In addition, as a practical matter, couriers, express couriers, and postal service personnel do not have access to the specimen chain of custody form since the form is inside the sealed package. Section 2.2(i) of the Mandatory Guidelines that discusses the transportation of a specimen to a laboratory has been revised to clarify this point.

One commenter recommended that the definitions in the Guidelines conform to the definitions established by the National Committee for Clinical Laboratory Standards (NCCLS) since the proposed definitions may be in conflict with the efforts of that nonprofit, educational organization. The Department fully supports the efforts of this committee to develop standard definitions since a common understanding of definitions is essential for maintaining a high level of performance within laboratory testing programs. The Department has revised the definitions in section 1.2 to ensure that they are consistent with those proposed currently by NCCLS. The Department has changed the proposed definitions for calibrator, control, and standard as well as included new definitions for donor, specimen, sample, and quality control sample. The Department also made appropriate changes in other sections of the Guidelines to ensure that the terms used were consistent with these new definitions. The Department notes, however, that these changes are not substantive, but rather are technical in nature to clarify the definitions. The Department believes these changes will eliminate the confusion expressed by several other commenters regarding the use of these terms in other sections of the Guidelines.

One commenter believes the proposed definition for the certifying scientist should specifically state that the individual understands chain of custody. The Department intended that the definition of certifying scientist include that the individual have a thorough understanding of chain of custody, since it was proposed that such individual have "training and experience in the theory and practice of all methods and procedures used in the laboratory." See section 1.2. However, in order to prevent any confusion, the definition has been changed to clarify this issue.

One commenter suggested that the Secretary require a certifying scientist to possess at least a masters degree, so they would be equal to experts presented by an employee who is contesting the result in court or in an administrative proceeding. Based on the Department's experience, there are numerous highly qualified individuals serving as certifying scientists who possess bachelors' degrees, and who have the expertise to testify as to the records they have certified. These certifying scientists do not need to be qualified as experts in litigation, as the defense may qualify someone else in the laboratory or outside the laboratory to perform this function, if necessary. Further, the Department believes that requiring higher educational requirements would place an unnecessary burden on the laboratories, as well as eliminate many qualified individuals from serving as certifying scientists.

One commenter believes the requirement to use an Office of Management and Budget (OMB) approved specimen chain of custody form requires the laboratories to use OMB approved laboratory chain of custody forms. This interpretation is incorrect. The Department proposed that such forms be used only for specimen chain of custody forms, *not* laboratory chain of custody forms. The Department believes that standard specimen chain of custody forms are important to ensure that collection sites have a consistent form so as to reduce any errors or incomplete documentation when filling out the forms.

One commenter noted that the Department's proposed definition of an immunoassay test is ambiguous and does not support the policy that allows using a second immunoassay test for specimens that are presumptively positive for amphetamines. Specifically, the term "initial test" was proposed to be defined as "[a]n immunoassay test to eliminate "negative" urine specimens from further consideration and to identify the class of drugs that requires confirmation." The Department agrees with the commenter that the definition is ambiguous. The Department supports allowing laboratories to perform multiple immunoassay tests for the same drug or drug class. Therefore, the Department has clarified the definition to ensure that further testing is consistent with section 2.4(e)(4) which permits conducting multiple initial tests.

2. Dilution/Adulteration Tests

Several commenters concurred with section 2.1(c) which clarifies that laboratories may conduct dilution/adulteration testing to determine the validity of the specimen while some commenters sought to have the Secretary define the specific tests to be conducted and require that such tests be performed. The issue regarding the types of dilution/adulteration testing to be performed has been highly controversial among forensic laboratory professionals since there is a lack of data to suggest that dilution/adulteration testing can clearly identify a donor who has intentionally taken a substance to affect the outcome of a drug test or has otherwise diluted or adulterated the specimen. At this time, the Department believes that such testing should remain optional and the selection of tests to be conducted for possible dilution/adulteration and the cutoff levels for such tests, if conducted, should be determined by the laboratories based on their best judgment.

Two commenters requested that the Department allow dilution/adulteration testing to be conducted at the collection

site. The Department believes that it is better able to monitor the performance of such testing when it is conducted by laboratory personnel, rather than require agencies to monitor such testing at the collection sites. During the laboratory inspection process, the Department is able to evaluate the laboratories' performance of such testing to ensure that tests are performed properly, chain of custody is not broken, and cross-contamination does not occur from one donor specimen to another which could impact the integrity of a specimen. The MRO can review the results of the dilution/adulteration tests and make a decision on the basis of the test and on his or her interview of the donor to determine whether a medical factor may have contributed to the results of such testing. In addition, disallowing the use of dilution/adulteration testing at the collection site ensures that agency employees are not unnecessarily subject to observed collection and thus protects the privacy of individuals to the maximum extent possible.

3. Specimen Collection Procedure

With regard to the specimen collection procedure, a number of commenters were highly supportive of reducing the required volume of a urine specimen from 60 mL to 30 mL as stated in section 2.2(f)(10). One commenter, however, expressed concern that 30 mL is insufficient when dealing with a specimen that is positive for more than one drug. That may be the case in some cases. Nevertheless, the number of specimens that are positive for more than one drug is very small and most volumes collected generally exceed 30 mL. The Department believes this reduced volume requirement will make it easier for an individual to provide a urine specimen with sufficient volume on the first attempt rather than requiring the collection of a second specimen after drinking a reasonable quantity of liquid. It is noted that the policy of combining additional urine, after drinking a reasonable amount of liquid, with a partial specimen (i.e., an insufficient volume of urine on the first void) has been eliminated. The Department believes the reduced volume requirements will ensure that a sufficient volume is collected on the first void and combining partial specimens will not be necessary.

One commenter expressed concern over the fact that the Mandatory Guidelines did not specify limitations or guidance as to the amount of liquid to be given a donor who could not provide a 30 mL urine specimen. The commenter expressed concerns regarding the possible risk of water intoxication if there is no limit established for the amount of liquid that can be provided. The Department concurs and has changed the example given in section 2.2(f)(10) to read "(e.g., an 8 oz glass of water every 30 minutes, but not to exceed a maximum of 24 oz)." The example provided describes a reasonable amount of liquid to be provided and the Department would expect collection sites to use reasonable care in its determination of the amount of liquid to provide donors.

Several commenters noted that the temperature range stated in the proposed revisions did not agree with the range stated in the introductory discussion of the proposed changes. A notice correcting the error was published in the **Federal Register** on March 1, 1993. The correct temperature range is "32°-38°/90°-100°F."

There was general agreement that the marginally wider temperature range will not adversely affect the ability to detect a donor who may possibly tamper with the specimen. Two commenters, however, believe that the lower limit of the temperature range should be increased. The Department does not agree with this recommendation. A urine specimen provided in a collection cup that is at room temperature will cool quickly; therefore, a narrow temperature range will significantly increase the number of specimens that will not satisfy the temperature range requirements. This would cause numerous unnecessary collections of second specimens and falsely raise suspicions that many donors have tampered with their specimens.

With regard to the collection of a urine specimen when using direct observation, one commenter suggested that the employee's agency choose the observer if there is no collection site person of the same gender available. The Department agrees and sections 2.2(f)(13), 2.2(f)(16), and 2.2(f)(23) have been revised to include this requirement. The Department believes that the agency will select an individual who will act responsibly and reliably so as not to substantiate any allegation to the contrary by an employee.

One commenter believes that only trained collectors should be involved in the collection procedure, especially when direct observation is required. The Department acknowledges that trained personnel should be involved in the collection of urine specimens; however, it is not always possible to ensure that a trained collection site person of the same gender will be available when a direct observation is required. Allowing the agency to select an individual to act as the observer, when there are unusual circumstances, ensures that the collection will occur promptly and as scheduled rather than delaying the collection unnecessarily.

One commenter believed that observed collection should never be used in any circumstances. The Department disagrees. The Department continues to believe that observed collection is justified and necessary when there exists reasonable suspicion to believe that the donor altered or substituted the specimen. Observed collections do not occur frequently. However, the Department believes that any invasion of a donor's privacy is greatly outweighed by public health and safety concerns in such cases.

One commenter recommended that we refer to the individual providing the urine specimen as the "donor." The Department concurs with the recommendation and has replaced the word "individual," when it refers to the person providing a urine specimen, with the word "donor" throughout the Guidelines. A definition for donor has been included in section 1.2. In addition, the use of the word "donor" is consistent with its use on the specimen chain of custody form.

One commenter suggested that the entire collection procedure be revised substantially to provide more specific guidance to agencies on the collection process. The Department believes the procedure, as described, provides sufficient guidance to the agencies on the collection process, including factors to ensure that urine specimens are collected properly and satisfy chain of custody requirements. The changes made in the Mandatory Guidelines with regard to the single specimen collection procedure and the optional split specimen procedure should clarify the procedures and, thereby, address many of the concerns raised by this commenter without completely revising and expanding the descriptions of the collection procedures.

Many commenters concurred with including an optional split specimen collection procedure. They believed it was important to include split specimens since the Omnibus Transportation Employee Testing Act of 1991, Title V of Public Law 102–143, requires using a split specimen collection procedure for industries regulated by the Department of Transportation (DOT). This is particularly important since Federal employees from a number of Departments will be subject to both the requirements of DOT (49 CFR Part 40) and the requirements of the Mandatory Guidelines and Executive Order 12564 (September 15, 1986).

Two commenters suggested allowing the use of two or three containers to collect split specimens. The Department agrees with this recommendation and has revised the collection procedure to indicate clearly that either a specimen bottle or a specimen container may be used when collecting urine specimens. However, when using a split specimen collection procedure, it is not acceptable for a donor to provide the split specimens by urinating directly into both Bottle A and Bottle B. The specimen must be provided by urinating into only one container or into Bottle A. After the temperature is measured, if the specimen was provided directly into Bottle A, an appropriate amount is poured into Bottle B. If a specimen container was used, appropriate amounts are poured from the specimen container into both Bottle A and Bottle B. For split specimen collections, this procedure ensures that the specimens in Bottle A and Bottle B are identical, it is easier to measure the temperature of a single specimen rather than to measure the temperature of two specimens that were collected in separate containers, and it is easier for a donor to provide one specimen in a single container/bottle rather than into two separate bottles.

It was suggested by several commenters that we specify the amount of urine to be poured into Bottle B. We concur with that recommendation and have changed section 2.2(h)(3) of the split specimen procedure to specify that a minimum of 15 mL of urine shall be poured into Bottle B. Since Bottle B will only be tested for a specific substance(s), 15 mL is sufficient to conduct the testing and to allow a sufficient quantity to be retained frozen if Bottle A is reported positive. Additionally, section 2.2(h)(1) has been changed to specify that a minimum of 45 mL of urine is required when using a split specimen collection procedure rather than the 30 mL minimum when using the single specimen collection procedure.

One commenter was concerned with the handling and storage of the split specimen (Bottle B) after the Bottle A specimen is shipped to the laboratory. We agree that the wording in section 2.2(h)(5) of the split specimen collection procedure regarding refrigerating the specimens was confusing and it has been revised. The Department believes that the most efficient and cost effective way to handle split specimens is to send both the Bottle A and Bottle B specimens to the laboratory at the same time including the appropriate specimen chain of custody forms. This procedure will ensure the integrity of both Bottle A and Bottle B. This procedure is also simpler and more cost effective than one which would require the collection site to retain Bottle B specimens until the results for the Bottle A specimens are reported by the MRO to the agency and the agency notifies the collection site to either discard the Bottle B specimens or to ship a specific Bottle B specimen to another certified laboratory. When both specimens are received by the laboratory, Bottle A is normally tested within one day and, if positive, both Bottle A and Bottle B can be placed in secure, refrigerated storage until the confirmatory test is completed. This procedure will ensure that both specimens are treated essentially the same and subject to similar storage conditions until the testing is completed.

Several commenters were concerned with the impact that a failed to reconfirm result on the Bottle B specimen would have on a donor since personnel action may have been taken based on an MRO verified positive result for Bottle A. Although a failed to reconfirm result for Bottle B requires the MRO to void the test result for Bottle A and an agency may be required to reverse any personnel action that may have been taken, we believe failed to reconfirm reports will occur infrequently and this possibility should not be the basis for an agency to delay any personnel action. The Department believes that removing an employee, for example, from a safety-sensitive position which may impact public health and safety outweighs the minimal possibility that the testing of Bottle B will not reconfirm the presence of a drug or metabolite.

In view of the comments, section 2.2(h)(6) has also been clarified to indicate the MRO's responsibility to report a positive result for Bottle A. When an MRO has verified the test of the first specimen bottle (Bottle A) as a positive result, the MRO must report the result to the agency without waiting for the donor to request that the Bottle B specimen be tested.

Several commenters expressed concern regarding the actions taken when a second laboratory fails to reconfirm the presence of a drug or metabolite in the second specimen bottle (Bottle B) in a split specimen collection. Since the Bottle B specimen is tested without regard to the cutoff levels, the result reported by the second laboratory is not reported as a negative or positive result, but reported as either reconfirmed or failed to reconfirm the presence of a drug or metabolite. The Department agrees that if this situation occurs, an investigation must be conducted. The Department has added this requirement in section 2.2(h)(8) of the Mandatory Guidelines and has required the MRO to notify the donor's agency. In addition, the Federal agency must contact the Secretary and the Secretary will investigate the failed to reconfirm result and attempt to determine the reason for the inconsistent results between Bottle A and Bottle B. HHS will report its findings to the Federal agency and ensure that appropriate action is taken to prevent the recurrence of the failed to reconfirm result.

Some commenters simply did not like permitting Federal agencies to have the option of a split specimen procedure, believing, for example, that the use of a split specimen procedure gives the perception of a lack of confidence in the results when using a single specimen collection, that the additional administrative and collection costs are not justified, and that there is an increased risk of administrative errors.

It should be noted that certain Federal employees are subject to both the Mandatory Guidelines and the Omnibus Transportation Employee Act of 1991, Title V of Public Law 102–431, (Omnibus Act) which requires split specimens. Therefore, the agencies must have the flexibility to collect split specimens as required by the Omnibus Act. Since Federal agencies may also request a waiver under section 1.1(e) of the Mandatory Guidelines and the Department has provided a number of agencies with a waiver to permit split specimens during the past 5 years, the Department believes including an optional split specimen collection procedure in the Mandatory Guidelines will ensure consistency among all agencies currently using split specimens and those wanting to implement split specimen collections. In addition, each agency should have the option of treating its employees equally rather than treating its employees under the Omnibus Act differently from the employees only subject to the Mandatory Guidelines.

With regard to the perception that the results from a single specimen collection are unreliable and not adequate to protect employee rights when compared to a split specimen collection, the Department is confident that the results from a single specimen collection are scientifically and legally supportable. This belief is based on the stringent requirements that have been established by the Mandatory Guidelines—that is, requiring the use of rigorous chain of custody procedures when handling and testing specimens; requiring laboratories to use qualified

and trained personnel, validated analytical testing procedures, and extensive internal quality control and quality assurance procedures; requiring laboratories to participate in a comprehensive certification program that includes performance testing samples and semi-annual inspections; and using MROs to ensure that procedures have been followed as required.

Although the split specimen procedures are designed to minimize administrative errors, the Department acknowledges that any time procedures are modified the risk of administrative errors increases. However, the use of a standard specimen chain of custody form should minimize such errors and the Department, through the inspection process, will monitor the laboratories' procedures in processing split specimens.

The procedures for split specimens are also designed to keep the administrative burden at a minimum. The Department believes that the paperwork for collection sites or laboratories will not increase much since the collection sites will be using a seven-part chain of custody form instead of a six-part form and sending both split specimens to the laboratory at the same time and in the same shipping container. This should minimize the additional cost and administrative burden on both collection sites and laboratories.

One commenter believed that split specimen collections create a potential to reverse results especially if there is a significant variation in the analytical sensitivities of the confirmatory tests used by each of the HHS-certified laboratories. The Department is aware of this potential and has provided guidance to the laboratories with regard to their capability to accurately quantitate and identify drugs at concentrations that are 40 percent of the confirmatory test levels. The Department believes this guidance and challenging laboratories with performance testing samples at these low concentrations will ensure that all laboratories have essentially the same sensitivity for each of the confirmatory tests.

Finally, one commenter requested guidance on whether the donor or agency would be responsible for paying the costs associated with analyzing the split specimen. The Department believes that the decision regarding financial responsibility for testing Bottle B is one the agencies must decide.

4. Certifying Test Results

One commenter stated that the proposed revision to section 2.3(b) that discusses "test validation" did not make it clear that a laboratory may use a certifying scientist who is only certified to review initial drug tests which are negative. Although this is the intent of this section and to ensure that no confusion exists, the title of section 2.3(b) has been changed to read "Certifying Test Results" and that section has been revised to state clearly that a laboratory may designate a certifying scientist(s) that is only qualified to certify results that are negative on the initial test. We note, however, that if a certifying scientist certifies confirmatory test results, the individual must have training and experience in all "procedures relevant to the results that the individual certifies." This includes both initial test and confirmatory test procedures. Changing the title of this section to read "Certifying Test Results" should also ensure that we are referring to the review and certification of specimen test results rather than the results associated with "validating" an analytical procedure before it is used to test specimens. The Department believes there was some confusion associated with the former title of this section.

5. Security and Chain of Custody

One commenter requested that the security requirements in section 2.4(a)(1), as proposed, be revised to allow emergency personnel access to all sections of the laboratory without escorts. The requirements for security pertain to limiting and documenting access under normal situations and providing escorts for authorized visitors, maintenance, and service personnel. For real emergencies, such as fires, it would be inappropriate to require the laboratory to provide an escort. This section has been changed to ensure that emergency personnel (such as firefighters) can have unescorted access similar to that authorized for inspectors. As suggested by the commenter, it would be acceptable for the laboratory to document the emergency and include, to the extent practicable, dates, time of entry and exit, and purpose of entry for all emergency response personnel. It must be noted that this exception does not apply to emergency "service" personnel, such as manufacturers' technical representatives who are called to repair an instrument or to conduct routine service.

6. Specimen Processing

One commenter noted that the word "standards" had been used incorrectly in section 2.4(d), as proposed, when stating the requirements for each initial and confirmatory batch. The Department concurs and has changed this section to state that each initial and confirmatory batch must satisfy the quality control requirements in sections 2.5(b) and 2.5(c), respectively, rather than using terms such as "standards" and "controls." Additionally, the last sentence of this section has been deleted because it is not entirely correct. Quality control samples must be known to laboratory technicians conducting the testing while only blind performance testing samples are unknown (i.e., the location in the batch, drug or metabolite present, and concentration). The requirements for laboratory blind performance testing samples and agency blind samples are discussed in section 2.5.

7. Marijuana Initial Test Level

Many respondents concurred with lowering the initial test level for marijuana metabolites from 100 to 50 ng/mL as proposed in section 2.4(e). However, one commenter claimed that the lowered cutoff concentration would identify the occasional user. The intent of Federal workplace drug testing programs is to identify individuals who use illegal substances regardless of whether they are regular or occasional users. Lowering the initial test level should increase the ability to detect any use of marijuana.

Another commenter questioned the impact that might result by the lowered cutoff concentration for those individuals who are exposed to passive inhalation (i.e., breathing the smoke exhaled by another individual smoking marijuana cigarettes). The Department does not believe that passive inhalation is a reasonable defense or that significant exposure can occur through passive inhalation to cause a urine specimen to be reported positive. A comprehensive study of passive inhalation conducted at the National Institute on Drug Abuse's Addiction Research Center in Baltimore (see Cone, E.J., et al., Passive Inhalation of Marijuana Smoke: Urinalysis and Room Air Levels of Delta-9-Tetrahydrocannabinol, Journal of Analytical Toxicology, 11: 89–96, 1987) indicates that it takes extensive exposure to extremely high concentrations under unrealistic conditions to cause a positive result; therefore, passive inhalation is not a

reasonable explanation for a positive result.

8. Initial and Confirmatory Tests

One commenter believed that the wording in section 2.4(e)(3), as proposed, conflicted with the authority to conduct dilution/adulteration tests as stated in section 2.1(c). The Department agrees that this section needs to be clarified. A laboratory may conduct dilution/adulteration tests on all specimens, whether they are positive or negative, and either before or after conducting the initial test. Section 2.4(e)(3) has been changed to clarify this policy.

Several commenters questioned the use of specimens that test negative on either the initial test or the confirmatory test for the laboratory's internal quality control program as proposed in sections 2.4(e)(3) and 2.4(f)(3). These commenters were concerned that the results may have been affected by such factors as medications that may have been taken, the health of the donors, and possible unknown problems with confirmation, thereby, making these specimens unsuitable as quality control samples. Several of these commenters recommended the use of certified negative urine or, at a minimum, confirming the negative pool by GC/MS prior to its use in a quality control program. In response to these concerns, the Department notes that the laboratory's operation must be consistent with good forensic laboratory practice (see section 3.20(c)) and such practice requires a laboratory to always certify a urine pool as negative before it is used to prepare negative samples or to prepare other quality control samples. If pooled urine does not satisfy the criteria for acceptability, it is discarded. Such certification of the urine will ensure the quality of a laboratory's internal quality control program.

9. Multiple Initial Tests

Two commenters supported the use of multiple initial tests as stated in section 2.4(e)(4), as proposed, while several commenters expressed concern with permitting the use of multiple testing. The Department believes that the use of multiple initial tests may reduce the number of presumptive positives that are forwarded to confirmatory testing that will not be confirmed and may allow obtaining a valid analytical result if a specimen is untestable on one immunoassay test. The use of multiple initial tests has been widely used with regard to testing for amphetamines and this policy should apply to all drugs.

In addition, there are reports that various substances, including prescription medications, can prevent obtaining a valid initial test result when using one immunoassay test. We believe it is appropriate to use a different immunoassay test in order to obtain a valid initial test result before reporting the specimen as "test not performed" and including an appropriate comment on the specimen chain of custody form. To clarify this issue, the example given in section 2.4(e)(4) has been changed to include the use of a second immunoassay test for untestable specimens.

It is noted that the last sentence of section 2.4(e)(4), as proposed, has been deleted since it is redundant with the requirements as stated in the first sentence of the section.

10. 200 ng/mL Amphetamine Reporting Rule

Six commenters concurred with the proposal in sections 2.4(f)(1) and 2.4(g)(2) that require a methamphetamine positive to contain at least 200 ng/mL of amphetamine before reporting the result as positive. Two commenters recommended that the 200 ng/mL rule be dropped entirely because they believed it is no longer relevant and the emphasis should be on improving the quality of the GC/MS confirmatory procedure. Seven commenters held similar views that the 200 ng/mL rule is too conservative and produces too many false negatives and recommended that it be lowered to either 100 or 50 ng/mL or at least equal to or greater than the limit of detection for amphetamine.

The Department believes that the 200 ng/mL requirement implemented as a temporary policy since December 22, 1990, is a necessary one to prevent false positive test results. On a special set of performance testing samples provided to the laboratories by the program, the Department found that the requirement adequately controlled all of the possible technical problems based on observations of results reported by the laboratories on that set of performance testing samples. The results indicated that a significant number of laboratories experienced chromatographic resolution problems when methamphetamine was present with ephedrine and 2% of the performance testing results evidenced a methamphetamine response when challenged with high concentrations of over-the-counter medications (e.g., ephedrine, pseudoephedrine, or phenylpropanolamine). These results indicated that the 200 ng/mL rule was effective in preventing any false positive results and should be continued. In addition, recent information provided by laboratories regarding their limits of quantitation and their results on performance testing samples that contained very low concentrations of amphetamine and methamphetamine indicate that 200 ng/mL continues to be the lowest concentration that most of the laboratories can reliably identify and quantitate for either methamphetamine or amphetamine. For these reasons, the Department believes using a lower concentration or eliminating the 200 ng/mL rule would increase the possibility for reporting a false positive methamphetamine result.

11. Reporting Results

One commenter was concerned that substituting "certifying scientist" in section 2.4(g)(5), as proposed, for the responsible person was making the certifying scientist responsible for the overall laboratory operations. We believe the commenter did not understand the purpose for changing the wording in this section. The use of "certifying scientist" in this section ensures that the requirement is consistent with current program practice. The responsible person continues to be responsible for the overall operation of the laboratory (see section 2.3(a)); however, section 2.4(g)(5) allows a certifying scientist to sign the external chain of custody form that is sent to the MRO.

12. Calibrators and Controls

One commenter raised concern with the materials used to prepare calibrators and controls which as described in section 2.4(n)(2) only allowed calibrators and controls to be prepared from pure drug standards. The commenter correctly indicated that calibrators and controls were available from other sources. The Department concurs and has revised the sentence to allow calibrators and controls to be prepared not only from pure drug reference materials, but from stock standard solutions obtained from other laboratories, or from commercial manufacturers. This change clarifies that laboratories have the flexibility to obtain "standards" used to prepare the calibrators and controls from different sources.

13. Potential Conflicts of Interest

Several commenters supported the policies in sections 2.4(n)(6) and 2.6(b), as proposed, that restricts the types of relationships between laboratories and Medical Review Officers to ensure there were no conflicts of interest. There were several comments submitted, however, stating that these requirements were not necessary since there is no evidence that MROs have not acted in the interest of

the donor or that current arrangements have adversely affected the ability of an MRO to monitor laboratories. The Department does not question the dedication and integrity of its certified laboratories and the MROs in carrying out their responsibilities and protecting the interests of the Federal agencies and donors. Nevertheless, the Department believes the issue must be addressed.

The MRO plays an essential role in the Federal drug testing program. See generally section 2.6 of the Mandatory Guidelines. The MRO is a licensed physician with a knowledge of substance abuse disorders who verifies whether the tests are positive or negative. In the case of a positive result reported by the laboratory, the Mandatory Guidelines require that the MRO contact the employee and personally interview the employee, i.e., in-person or by telephone, to determine whether alternate medical explanations would explain a positive result. See section 2.6(c). During the course of such interview and possibly through having the specimen retested, the MRO may identify false positive test results. In such a case, the MRO is required to contact the Secretary so that the Department can conduct an investigation into the matter and take whatever action is necessary to prevent such a result from occurring in the future. See section 2.6(g).

Because the MRO plays such an essential role, the Department believes any relationship that may be construed as a potential conflict of interest may be sufficient to undermine the integrity of the program. Every Federal agency, employee, and job applicant must have complete assurance that test results will be thoroughly reviewed and, if errors are discovered, that the MRO will report the error and an appropriate investigation and corrective action will be taken.

14. Laboratory Quality Control Requirements for Initial Tests

There were several comments submitted regarding the requirements in section 2.5(b), as proposed, for quality control samples when conducting the initial test. The commenters believed the proposed requirements were confusing and suggested using different terms to describe the types of quality controls that must be included in each initial test batch. The Department concurs that the quality control requirements in this section were confusing and they have been revised based on the definitions in section 1.2. It should be noted the changes to this section only clarify the requirements for quality control samples; the actual policy has not changed from the original Mandatory Guidelines. See section 2.5(b) of 53 FR 11979, 11984 (April 11, 1988). We have also revised the quality control requirements for each confirmatory test batch in section 2.5(c) using the new definitions in section 1.2 without changing the policy as compared to the original Mandatory Guidelines. See section 2.5(c) of 53 FR 11979, 11985 (April 11, 1988).

In addition, it was noted that there was an error in the requirement that each initial test batch must contain a minimum of 20% quality control samples. A correction stating that 10% was the minimum amount was published in the **Federal Register** on March 1, 1993.

15. Agency Blind Sample Program

A number of commenters supported reducing the requirements for agency blind samples from 10% to 3% as indicated in section 2.5(d)(2). One commenter suggested retaining the 10% minimum and one commenter suggested establishing a minimum number of blind samples per quarter for organizations with a small test population. The Department believes the reduced requirement will not have a significant impact on the ability of an agency to evaluate its entire drug testing program; however, there is no prohibition for an agency to use a higher percentage or a higher number of blind samples to be submitted with donor specimens.

The Department has also changed the requirements for the number of blind samples to be submitted with donor specimens during the initial 90-day period of any new contract to conform with reducing the requirements of blind samples as provided by section 2.5(d)(2). Our experience during the past 5 years suggests that it is not necessary to submit large numbers of blind samples to verify the testing conducted by the certified laboratories.

16. Reanalysis Authorized

Two commenters expressed concern with the retesting policy proposed in section 2.6(e) which provided that only the MRO was authorized to order a reanalysis of the original specimen or Bottle B from a split specimen collection. One commenter believes the donor was authorized to request a retest of the original specimen. It is the Department's position that if an MRO cannot verify a positive result for whatever reason, only the MRO is authorized to request the retest of the original specimen since the MRO is the only individual who has all the information necessary to identify a particular specimen in a laboratory.

Another commenter pointed out an inconsistency between the retest policy proposed in this section and the policy proposed for testing Bottle B from a split specimen collection as described in section 2.2(h)(6) which states that only the donor may request through the MRO that the second specimen bottle (Bottle B) be tested. The Department agrees that there is an inconsistency in the proposed policies because we inadvertently referred to the Bottle B specimen in section 2.6(e) rather than the Bottle A specimen. Section 2.6(e) has been changed to clarify that only the MRO may request the retest of either a single specimen or a Bottle A specimen when using a split specimen collection. The procedures for the testing of Bottle B remain as proposed in section 2.2(h)(6)—that is, only the donor may request through the MRO that Bottle B be tested.

17. Reporting Final Results to the Agency

One commenter suggested that section 2.6(h), as proposed, which clarifies the requirement that the MRO provide written reports to the agency on positive and negative drug test results would significantly increase the administrative costs associated with the program and recommended that the MRO be required to provide written reports to the agency for positive results only. The Department disagrees. Written reports from the MRO to the agency on all specimens tested ensures that all specimens have been tested and the results of all specimens have been reviewed by the MRO. In addition, the Department believes that this requirement for written reports to the agency does not prevent the MRO from reporting several results on the same correspondence sent to the agency and, therefore, should not significantly affect the cost associated with the MRO review of drug testing results.

18. Certified Laboratories Notifying Private Sector Clients

Two commenters were concerned that the policy in section 3.4 did not adequately ensure that a laboratory would inform clients if and when the laboratory did not satisfy the certification requirements. The Department concurs that a laboratory must inform its clients when its certification has been suspended. Since the program began, this notification has been required and is set out in the suspension letter that is sent to the laboratory.

However, the intent of the requirement in section 3.4 that certified laboratories clearly inform clients when procedures followed do not conform to the Mandatory Guidelines is not related to suspension and/or proposed revocation actions. The purpose is to ensure that unregulated, private sector clients are aware that the laboratory may be using procedures that are not subject to or in accordance with the Mandatory Guidelines. The Department believes that a certified laboratory must not use its certification to promote itself as such if, in fact, it uses procedures that do not comply with the Mandatory Guidelines for such clients. This section has been revised to clarify this requirement.

19. Performance Testing Program

There were several comments submitted regarding changing the performance testing (PT) program from a bimonthly program to a quarterly program as stated in various sections of subpart C. One commenter disagreed with changing the performance testing program to a quarterly program because this would prolong the recertification process and suggested that a monthly PT program would be more appropriate. The Department has no intention of changing the initial certification procedures or to change the procedures when a laboratory has been suspended and must successfully analyze performance testing samples prior to having the suspension lifted. In addition, the Department believes a monthly PT program does not allow sufficient time for a laboratory to receive its results on a set of PT samples, analyze its performance, and initiate appropriate corrective action before the next cycle of PT samples.

One commenter was concerned that adopting a quarterly PT program without changing the criteria for determining acceptable performance, as set out in section 3.19, would increase the period for evaluating a laboratory's performance to 9 months. The Department concurs that the criteria for determining acceptable performance, that is, performance on 3 consecutive quarterly PT cycles, would unduly lengthen the time before corrective action may be taken. Since the total number of PT samples in 2 cycles of the quarterly PT program will be essentially the same as those for 3 cycles of the bimonthly PT program, it is appropriate to establish acceptable performance criteria based on performance over 2 consecutive cycles of quarterly PT samples. All criteria in section 3.19 that pertain to evaluating the performance of certified laboratories have been changed to evaluate acceptable performance over 2 consecutive cycles rather than over 3 consecutive cycles, which retains the 6-month evaluation period.

One commenter agreed with the change in section 3.19(b)(4), as proposed, that would allow a certified laboratory to have one quantitative result greater than 50% from the target value without requiring program action against the laboratory. However, the commenter is concerned that the cause for the error may not be investigated since program action is not taken against the laboratory. The Department did not intend that this change would prevent any investigation into the cause for the error or that the laboratory would not be required by the Department to make a concerted effort to determine the cause for the error and to take appropriate corrective action.

One commenter believes that the overall costs for the certification program may be decreased without compromising the high quality of the program by increasing the PT challenges to a monthly program and decreasing the maintenance inspections to once a year. The Department disagrees with this proposal because it is important to inspect laboratories at least every six months to ensure that the laboratory has continued to satisfy the requirements of the Mandatory Guidelines and for the inspectors to review the results reported for the PT samples. If corrective action is necessary, it will be more timely than if inspections were on a yearly basis. In addition, the existence of a significant problem over a long period of time would possibly jeopardize the results of many more personnel specimens.

20. Corrective Action by Certified Laboratories

Several commenters expressed concern that section 3.12(c), as proposed, would give the Secretary the authority to review all results and activities associated with a laboratory's testing of specimens for private sector, unregulated clients. This was not the intent and the section has been changed to indicate that the Secretary has authority to review results for specimens collected for private sector clients that were tested by the certified laboratory under the Mandatory Guidelines to the extent necessary to ensure the full reliability of drug testing for Federal agencies.

21. Recertification

One commenter was concerned with the policy contained in section 3.16, as proposed, because the commenter believed the procedure to regain certification after the laboratory's certification has been revoked would be prolonged given that the maintenance PT program has been reduced to a quarterly program. The commenter misunderstood that provision. The Department has not changed the initial certification procedure (section 3.16) under which a laboratory that had its certification revoked must proceed to regain certification. Thus, such a laboratory will proceed as in the past and must satisfactorily perform in each phase of the initial certification process. However, the first sentence of section 3.16 has been changed to indicate that the recertification policy applies only when a laboratory has its certification revoked.

22. Inspection Performance

One commenter was concerned that the meaning of the phrase "consistent with good forensic laboratory practice" in section 3.20(c), as proposed, was too subjective. The commenter believes that each inspection team interprets laboratory's procedures differently, thereby, what is acceptable during one inspection may be unacceptable during the next inspection. We do not concur with this assessment of the inspection process. Although there is some inherent subjectivity in the inspection process when applying certain criteria under the Mandatory Guidelines, the inspectors are provided clear guidance on what is to be inspected and what is acceptable and unacceptable. The Department requires trained, qualified inspectors to use a comprehensive checklist consisting of some 300 questions to evaluate a laboratory's procedures. They are asked to respond "yes" or "no" to the questions and then provide comments if the answer is unacceptable. This checklist ensures that each inspector is reviewing essentially all of the same laboratory documents and results. The inspection reports are reviewed by the Department to ensure that program requirements and policies are applied consistently among all laboratories. In addition, it is the responsibility of each laboratory to review the Mandatory Guidelines, to be aware of what is to be inspected by reviewing the checklist and other program documents, to correct deficiencies, and to use good forensic laboratory practice in its testing program.

One commenter suggested that the word "all" be deleted from the second sentence in section 3.20(c), as proposed, because a laboratory is not required to correct "all" deficiencies identified by the inspectors. We concur with the comment and have deleted the word "all." The Department's policy has always been to include minor

deficiencies or concerns in the critique developed from the inspection reports and give the laboratory the option to take whatever additional corrective action it deems appropriate for these minor deficiencies or concerns.

23. Procedures for Review of Suspension or Proposed Revocation of a Certified Laboratory

One commenter suggests that the definition of appellant in section 4.2, as proposed, is unclear and believes that the review procedures only apply when there is a proposed revocation. The Department disagrees with this position. The Department believes that principles of fairness necessitate allowing laboratories to seek internal reviews not only of proposed revocations but also internal reviews of immediate suspensions.

24. Other Minor Changes

In addition to the changes discussed above, there were several minor changes made in other sections. The acronym "MRO" has been added to the definition for Medical Review Officer in section 1.2. Since the original Guidelines were published, the "MRO" acronym has become a common and accepted way to refer to a physician performing this function. We have replaced "Medical Review Officer" with "MRO" throughout the Guidelines.

Section 2.5(d)(4) was changed to clarify that an agency shall investigate any unsatisfactory blind performance testing results and submit its findings to HHS rather than HHS conducting the initial investigation. The Department believes the agency must gather all pertinent information and investigate the reason before HHS is contacted to continue the investigation and to ensure that the laboratory has taken corrective action.

Section 2.6(c) has been simplified to require the MRO to send results only to the designated person in the agency rather than to both agency's Employee Assistance Program and to the agency's management official. The Department believes that the agency should have the discretion to determine who should receive results.

Section 3.3 was clarified to read that a laboratory must satisfy all pertinent provisions of the Guidelines in order to maintain certification while the original requirement only addressed satisfying the provisions in order to qualify for certification.

Section 3.15(b) was revised to conform with the review procedure in new subpart D which allows laboratories the opportunity for an informal review of a program action within 30 days of the date the laboratory received the notice, or if seeking an expedited review, within 3 days of the date the laboratory received the notice.

Two commenters noted that section 3.18(b) referred to a subset of PT samples as "directed specimens" rather than as "retest samples" which is current program terminology. We concur with the comment submitted and have revised the section to refer to these PT samples as "retest samples."

Other appropriate minor editorial changes have been made for clarity and consistency.

Information Collection Requirements

Any comments related to the Paperwork Reduction Act of 1980 may be sent to the HHS Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Information collection and recordkeeping requirements which would be imposed on laboratories engaged in urine drug testing for Federal agencies concern quality assurance and quality control; security and chain of custody; documentation; reports; performance testing; and inspections as set out in sections 3.7, 3.8, 3.10, 3.11, 3.17, and 3.20. To facilitate ease of use and uniform reporting, a specimen chain of custody form has been developed as referenced in sections 1.2, 2.2(c), and 2.2(f).

The information collection and recordkeeping requirements contained in these Mandatory Guidelines have been submitted to the Office of Management and Budget for review under section 3504(h) of the Paperwork Reduction Act of 1980.

Dated: February 7, 1994.

Philip R. Lee,

Assistant Secretary for Health.

Dated: March 16, 1994.

Donna E. Shalala,

Secretary.

The Mandatory Guidelines as revised are hereby adopted in accordance with Executive Order 12564 and section 503 of Pub. L. 100–71. For the public's convenience the Mandatory Guidelines as revised are set out in full as follows:

Mandatory Guidelines for Federal Workplace Drug Testing Programs

Subpart A—General

Subpart B—Scientific and Technical Requirements

Subpart C—Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies

Subpart D—Procedures for Review of Suspension or Proposed Revocation of a Certified Laboratory

Authority: E.O. 12564 and Sec. 503 of Pub. L. 100–71.

Subpart A—General

Section 1.1 Applicability.

(a) These mandatory guidelines apply to:

(1) Executive Agencies as defined in 5 U.S.C. 105;

(2) The Uniformed Services, as defined in 5 U.S.C. 2101(3) (but excluding the Armed Forces as defined in 5 U.S.C. 2101(2));

(3) And any other employing unit or authority of the Federal Government except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches.

(b) Subpart C of these Guidelines (which establishes laboratory certification standards) applies to any laboratory which has or seeks certification to perform urine drug testing for Federal agencies under a drug testing program conducted under E.O. 12564. Only laboratories certified under these standards are authorized to perform urine drug testing for Federal agencies.

(c) The Intelligence Community, as defined by Executive Order No. 12333, shall be subject to these Guidelines only to the extent agreed to by the head of the affected agency.

(d) These Guidelines do not apply to drug testing conducted under legal authority other than E.O. 12564, including testing of persons in the criminal justice system, such as arrestees, detainees, probationers, incarcerated persons, or parolees.

(e) Agencies may not deviate from the provisions of these Guidelines without the written approval of the Secretary. In requesting approval for a deviation, an agency must petition the Secretary in writing and describe the specific provision or provisions for which a deviation is sought and the rationale therefor. The Secretary may approve the request upon a finding of good cause as determined by the Secretary.

(f) Agencies shall purchase drug testing services only from laboratories certified by HHS or an HHS-recognized certification program in accordance with these Guidelines.

Section 1.2 Definitions

For purposes of these Guidelines the following definitions are adopted:

Aliquot. A fractional part of a specimen used for testing. It is taken as a sample representing the whole specimen.

Calibrator. A solution of known concentration used to calibrate a measurement procedure or to compare the response obtained with the response of a test specimen/sample. The concentration of the analyte of interest in the calibrator is known within limits ascertained during its preparation. Calibrators may be used to establish a calibration curve over a range of interest.

Certifying Scientist. An individual with at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent who reviews all pertinent data and quality control results. The individual shall have training and experience in the theory and practice of all methods and procedures used in the laboratory, including a thorough understanding of chain of custody procedures, quality control practices, and analytical procedures relevant to the results that the individual certifies. Relevant training and experience shall also include the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial action to be taken in response to test systems being out of control-limits or detecting aberrant test or quality control results.

Chain of Custody. Procedures to account for the integrity of each urine specimen by tracking its handling and storage from point of specimen collection to final disposition of the specimen. These procedures shall require that an Office of Management and Budget (OMB) approved specimen chain of custody form be used from time of collection to receipt by the laboratory and that upon receipt by the laboratory an appropriate laboratory chain of custody form(s) account for the specimens and samples within the laboratory. Chain of custody forms shall, at a minimum, include an entry documenting date and purpose each time a specimen or sample is handled or transferred and identifying every individual in the chain of custody.

Collection Site. A place designated by the agency where individuals present themselves for the purpose of providing a specimen of their urine to be analyzed for the presence of drugs.

Collection Site Person. A person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the urine specimen provided by those individuals. A collection site person shall have successfully completed training to carry out this function.

Confirmatory Test. A second analytical procedure to identify the presence of a specific drug or metabolite which is independent of the initial test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability and accuracy. (At this time gas chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine.)

Control. A sample used to monitor the status of an analysis to maintain its performance within desired limits.

Donor. The individual from whom a urine specimen is collected.

Initial Test (also known as Screening Test). An immunoassay test to eliminate "negative" urine specimens from further consideration and to identify the presumptively positive specimens that require confirmation or further testing.

Laboratory Chain of Custody Form. The form(s) used by the testing laboratory to document the security of the specimen and all aliquots of the specimens during testing and storage by the laboratory. The form, which may account for an entire laboratory test batch, shall include the names and signatures of all individuals who accessed the specimens or aliquots and the date and purpose of the access.

Medical Review Officer (MRO). A licensed physician responsible for receiving laboratory results generated by an agency's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result together with his or her medical history and any other relevant biomedical information.

Quality Control Sample. A sample used to evaluate whether or not the analytical procedure is operating within predefined tolerance limits. Calibrators, controls, negative urine samples, and blind samples are collectively referred to as "quality control samples" and each as a "sample."

Reason to Believe. Reason to believe that a particular individual may alter or substitute the urine specimen as provided in section 4(c) of E.O. 12564.

Sample. A representative portion of a urine specimen or quality control sample used for testing.

Secretary. The Secretary of Health and Human Services or the Secretary's designee. The Secretary's designee may be a contractor or other recognized organization which acts on behalf of the Secretary in implementing these Guidelines.

Specimen. The portion of urine that is collected from a donor.

Specimen Chain of Custody Form. An OMB approved form used to document the security of the specimen from time of collection until receipt by the laboratory. This form, at a minimum, shall include specimen identifying information, date and location of collection, name and signature of

collector, name of testing laboratory, and the names and signatures of all individuals who had custody of the specimen from time of collection until the specimen was prepared for shipment to the laboratory.

Standard. A reference material of known purity or a solution containing a reference material at a known concentration.

Section 1.3 Future Revisions

In order to ensure the full reliability and accuracy of drug assays, the accurate reporting of test results, and the integrity and efficacy of Federal drug testing programs, the Secretary may make changes to these Guidelines to reflect improvements in the available science and technology. These changes will be published in final as a notice in the **Federal Register**.

Subpart B—Scientific and Technical Requirements

Section 2.1 The Drugs

(a) The President's Executive Order 12564 defines "illegal drugs" as those included in Schedule I or II of the Controlled Substances Act (CSA), but not when used pursuant to a valid prescription or when used as otherwise authorized by law. Hundreds of drugs are covered under Schedule I and II and while it is not feasible to test routinely for all of them, Federal drug testing programs shall test for drugs as follows:

(1) Federal agency applicant and random drug testing programs shall at a minimum test for marijuana and cocaine;

(2) Federal agency applicant and random drug testing programs are also authorized to test for opiates, amphetamines, and phencyclidine; and

(3) When conducting reasonable suspicion, accident, or unsafe practice testing, a Federal agency may test for any drug listed in Schedule I or II of the CSA.

(b) Any agency covered by these guidelines shall petition the Secretary in writing for approval to include in its testing protocols any drugs (or classes of drugs) not listed for Federal agency testing in paragraph (a) of this section. Such approval shall be limited to the use of the appropriate science and technology and shall not otherwise limit agency discretion to test for any drugs covered under Schedule I or II of the CSA.

(c) Urine specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines shall be used only to test for those drugs included in agency drug-free workplace plans and may not be used to conduct any other analysis or test unless otherwise authorized by law except if additional testing is required to determine the validity of the specimen. Urine that tests negative by initial or confirmatory testing may, however, be pooled for use in the laboratory's internal quality control program.

(d) These Guidelines are not intended to limit any agency which is specifically authorized by law to include additional categories of drugs in the drug testing of its own employees or employees in its regulated industries.

Section 2.2 Specimen Collection Procedures

(a) *Designation of Collection Site.* Each agency drug testing program shall have one or more designated collection sites which have all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and shipping or transportation of urine specimens to a certified drug testing laboratory.

(b) *Security.* Procedures shall provide for the designated collection site to be secure. If a collection site facility is dedicated solely to urine collection, it shall be secure at all times. If a facility cannot be dedicated solely to drug testing, the portion of the facility used for testing shall be secured during drug testing.

(c) *Chain of Custody.* Chain of custody standardized forms shall be properly executed by authorized collection site personnel upon receipt of specimens. Handling and transportation of urine specimens from one authorized individual or place to another shall always be accomplished through chain of custody procedures. Every effort shall be made to minimize the number of persons handling specimens.

(d) *Access to Authorized Personnel Only.* No unauthorized personnel shall be permitted in any part of the designated collection site when urine specimens are collected or stored.

(e) *Privacy.* Procedures for collecting urine specimens shall allow individual privacy unless there is reason to believe that a particular donor may alter or substitute the specimen to be provided.

(f) *Integrity and Identity of Specimen.* Agencies shall take precautions to ensure that a urine specimen not be adulterated or diluted during the collection procedure and that information on the urine bottle and on the specimen chain of custody form can identify the donor from whom the specimen was collected. The following minimum precautions shall be taken to ensure that unadulterated specimens are obtained and correctly identified:

(1) To deter the dilution of specimens at the collection site, toilet bluing agents shall be placed in toilet tanks wherever possible, so the reservoir of water in the toilet bowl always remains blue. There shall be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs.

(2) When a donor arrives at the collection site, the collection site person shall request the donor to present photo identification. If the donor does not have proper photo identification, the collection site person shall contact the supervisor of the donor, the coordinator of the drug testing program, or any other agency official who can positively identify the donor. If the donor's identity cannot be established, the collection site person shall not proceed with the collection.

(3) If the donor fails to arrive at the assigned time, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(4) The collection site person shall ask the donor to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the donor's urine specimen. The collection site person shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments. The donor may retain his or her wallet.

(5) The donor shall be instructed to wash and dry his or her hands prior to urination.

(6) After washing hands, the donor shall remain in the presence of the collection site person and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent, or any other materials which could be used to adulterate the specimen.

(7) The collection site person shall give the donor a clean specimen bottle or specimen container. The donor may provide his/her specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy.

(8) The collection site person shall note any unusual behavior or appearance on the specimen chain of custody form.

(9) In the exceptional event that an agency-designated collection site is not accessible and there is an immediate requirement for specimen collection (e.g., an accident investigation), a public rest room may be used according to the following procedures: A person of the same gender as the donor shall accompany the donor into the public rest room which shall be made secure during the collection procedure. If possible, a toilet bluing agent shall be

placed in the bowl and any accessible toilet tank. The collection site person shall remain in the rest room, but outside the stall, until the specimen is collected. If no bluing agent is available to deter specimen dilution, the collection site person shall instruct the donor not to flush the toilet until the specimen is delivered to the collection site person. After the collection site person has possession of the specimen, the donor will be instructed to flush the toilet and to participate with the collection site person in completing the chain of custody procedures.

(10) Upon receiving the specimen from the donor, the collection site person shall determine the volume of urine in the specimen bottle/container.

(i) If the volume is greater than 30 milliliters (mL), the collection site person will proceed with step (11) below.

(ii) If the volume is less than 30 mL and the temperature is within the acceptable range specified in step (13) below, the specimen is discarded and a second specimen shall be collected. The donor may be given a reasonable amount of liquid to drink for this purpose (e.g., an 8 oz glass of water every 30 min, but not to exceed a maximum of 24 oz). If the donor fails for any reason to provide 30 mL of urine for the second specimen collected, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(iii) If the volume is less than 30 mL and the temperature is outside the acceptable range specified in step (13) below, a second specimen shall be collected using the procedure specified in step (13) below.

(11) After the specimen has been provided and submitted to the collection site person, the donor shall be allowed to wash his or her hands.

(12) Immediately after the specimen is collected, the collection site person shall measure only the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement is critical and in no case shall exceed 4 minutes.

(13) If the temperature of the specimen is outside the range of 32°–38 °C/90°–100 °F, that is a reason to believe that the donor may have altered or substituted the specimen, and another specimen shall be collected under direct observation of a person of the same gender and both specimens shall be forwarded to the laboratory for testing. The agency shall select the observer if there is no collection site person of the same gender available. A donor may volunteer to have his or her oral temperature taken to provide evidence to counter the reason to believe the donor may have altered or substituted the specimen caused by the specimen's temperature falling outside the prescribed range.

(14) Immediately after the specimen is collected, the collection site person shall also inspect the specimen to determine its color and look for any signs of contaminants. Any unusual findings shall be noted on the specimen chain of custody form.

(15) All specimens suspected of being adulterated or diluted shall be forwarded to the laboratory for testing.

(16) When there is any reason to believe that a donor may have altered or substituted the specimen to be provided, another specimen shall be obtained as soon as possible under the direct observation of a person of the same gender and both specimens shall be forwarded to the laboratory for testing. The agency shall select the observer if there is no collection site person of the same gender available.

(17) Both the donor and the collection site person shall keep the specimen bottle/container in view at all times prior to its being sealed and labeled. If the specimen is transferred from a specimen container to a specimen bottle, the collection site person shall request the donor to observe the transfer of the specimen and the placement of the tamper-evident seal/tape on the bottle. The tamper-evident seal may be in the form of evidence tape, a self-sealing bottle cap with both a tamper-evident seal and unique coding, cap and bottle systems that can only be sealed one time, or any other system that ensures any tampering with the specimen will be evident to laboratory personnel during the accessioning process.

(18) The collection site person and the donor shall be present at the same time during procedures outlined in paragraphs (f)(19)–(f)(22) of this section.

(19) The collection site person shall place securely on the specimen bottle an identification label which contains the date, the donor's specimen number, and any other identifying information provided or required by the agency.

(20) The donor shall initial the identification label on the specimen bottle for the purpose of certifying that it is the specimen collected from him or her.

(21) The collection site person shall enter on the specimen chain of custody form all information identifying the specimen.

(22) The donor shall be asked to read and sign a statement on the specimen chain of custody form certifying that the specimen identified as having been collected from him or her is in fact that specimen he or she provided.

(23) Based on a reason to believe that the donor may alter or substitute the specimen to be provided, a higher level supervisor shall review and concur in advance with any decision by a collection site person to obtain a specimen under direct observation. The person directly observing the specimen collection shall be of the same gender. The agency shall select the observer if there is no collection site person of the same gender available.

(24) The collection site person shall complete the specimen chain of custody form.

(25) The urine specimen and specimen chain of custody form are now ready for shipment. If the specimen is not immediately prepared for shipment, it shall be appropriately safeguarded during temporary storage.

(26) While any part of the above chain of custody procedures is being performed, it is essential that the urine specimen and custody documents be under the control of the involved collection site person. If the involved collection site person leaves his or her work station momentarily, the urine specimen and specimen chain of custody form shall be taken with him or her or shall be secured. After the collection site person returns to the work station, the custody process will continue. If the collection site person is leaving for an extended period of time, the specimen shall be packaged for mailing before he or she leaves the site.

(g) *Collection Control.* To the maximum extent possible, collection site personnel shall keep the donor's specimen bottle within sight both before and after the donor has urinated. After the specimen is collected, it shall be properly sealed and labeled. A specimen chain of custody form shall be used for maintaining control and accountability of each specimen. The date and purpose shall be documented on a specimen chain of custody form each time a specimen is handled or transferred and every individual in the chain shall be identified. Every effort shall be made to minimize the number of persons handling specimens.

(h) *Split Specimens.* An agency may, but is not required to, use a split specimen method of collection. If the urine specimen is split into two specimen bottles (hereinafter referred to as Bottle A and Bottle B) the following procedure shall be used:

(1) The donor shall urinate into either a specimen bottle or specimen container. The collection site person, in the presence of the donor, after determining specimen temperature, pours the urine into two specimen bottles that are labeled Bottle A and Bottle B or, if Bottle A was used to collect the specimen, pours an appropriate amount into Bottle B. A minimum of 45 mL of urine is required when using a split specimen procedure, i.e., 30 mL for Bottle A and 15 mL for Bottle B.

(2) The Bottle A specimen, containing a minimum of 30 mL of urine, is to be used for the drug test. If there is no additional urine available for the second specimen bottle (Bottle B), the first specimen bottle (Bottle A) shall nevertheless be processed for testing.

(3) A minimum of 15 mL of urine shall be poured into the second specimen bottle (Bottle B).

(4) All requirements of this part shall be followed with respect to Bottle A and Bottle B, including the requirements that a copy of the chain of custody form accompany each bottle processed under split sample procedures.

(5) The collection site shall send the split specimens (Bottle A and Bottle B) at the same time to the laboratory that will be testing the Bottle A specimen.

(6) If the test of the first specimen bottle (Bottle A) is verified positive by the MRO, the MRO shall report the result to the agency. Only the donor may request through the MRO that the second specimen bottle (Bottle B) be tested in an HHS-certified laboratory for presence of the drug(s) for which a positive result was obtained in the test of the first specimen bottle (Bottle A). The MRO shall honor such a request if it is made within 72 hours of the donor's having received notice that he or she tested positive. The result of this test is transmitted to the MRO without regard to the cutoff levels used to test the first specimen bottle (Bottle A).

(7) Any action taken by a Federal agency as a result of an MRO verified positive drug test (e.g., removal from performing a safety-sensitive function) may proceed whether Bottle B is or is not tested.

(8) If the result of the test on the second specimen bottle (Bottle B) fails to reconfirm the result reported for Bottle A, the MRO shall void the test result for Bottle A and the donor shall re-enter the group subject to random testing as if the test had not been conducted. The MRO shall notify the Federal agency when a failed to reconfirm has occurred and the agency shall contact the Secretary. The Secretary will investigate the failed to reconfirm result and attempt to determine the reason for the inconsistent results between Bottle A and Bottle B. HHS will report its findings to the agency including recommendations and/or actions taken to prevent the recurrence of the failed to reconfirm result.

(i) *Transportation to Laboratory.* Collection site personnel shall arrange to ship the collected specimens to the drug testing laboratory. The specimens shall be placed in containers designed to minimize the possibility of damage during shipment, for example, specimen boxes or padded mailers; and those containers shall be securely sealed to eliminate the possibility of undetected tampering. The collection site personnel shall ensure that the specimen chain of custody form is enclosed within each container sealed for shipment to the drug testing laboratory. Since specimens are sealed in packages that would indicate any tampering during transit to the laboratory and couriers, express carriers, and postal service personnel do not have access to the chain of custody forms, there is no requirement that such personnel document chain of custody for the package during transit.

Section 2.3 Laboratory Personnel

(a) *Day-to-Day Management.* (1) The laboratory shall have a responsible person (RP) to assume professional, organizational, educational, and administrative responsibility for the laboratory's urine drug testing facility.

(2) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are:

(i) Certification as a laboratory director by the State in forensic or clinical laboratory toxicology; or

(ii) A Ph.D. in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology; or

(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology; and

(iv) In addition to the requirements in (i), (ii), and (iii) above, minimum qualifications also require:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse, and

(B) Appropriate training and/or experience in forensic applications of analytical toxicology, e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors which qualify the individual as an expert witness in forensic toxicology.

(3) This individual shall be engaged in and responsible for the day-to-day management of the drug testing laboratory even where another individual has overall responsibility for an entire multispeciality laboratory.

(4) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. He or she shall assure the continued competency of laboratory personnel by documenting their inservice training, reviewing their work performance, and verifying their skills.

(5) This individual shall be responsible for the laboratory's having a procedure manual which is complete, up-to-date, available for personnel performing tests, and followed by those personnel. The procedure manual shall be reviewed, signed, and dated by this responsible person whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the drug testing laboratory. Copies of all procedures and dates on which they are in effect shall be maintained. (Specific contents of the procedure manual are described in section 2.4(n)(1))

(6) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; for maintaining acceptable analytical performance for all controls and standards; for maintaining quality control testing; and for assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(7) This individual shall be responsible for taking all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual shall ensure that sample results are not reported until all corrective actions have been taken and he or she can assure that the results provided are accurate and reliable.

(b) *Certifying Test Results.* The laboratory's urine drug testing facility shall have a certifying scientist(s), as defined in section 1.2, who reviews all pertinent data and quality control

results in order to attest to the validity of the laboratory's test reports. A laboratory may designate certifying scientists that are qualified to certify only results that are negative on the initial test and certifying scientists that are qualified to certify both initial and confirmatory tests.

(c) *Day-to-Day Operations and Supervision of Analysts.* The laboratory's urine drug testing facility shall have an individual(s) to be responsible for day-to-day operations and to supervise the technical analysts. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

(d) *Other Personnel.* Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(e) *Training.* The laboratory's urine drug testing program shall make available continuing education programs to meet the needs of laboratory personnel.

(f) *Files.* Laboratory personnel files shall include: resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; and results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate.

Section 2.4 Laboratory Analysis Procedures

(a) *Security and Chain of Custody.* (1) Drug testing laboratories shall be secure at all times. They shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory processes or to areas where records are stored. Access to these secured areas shall be limited to specifically authorized individuals whose authorization is documented. With the exception of personnel authorized to conduct inspections on behalf of Federal agencies for which the laboratory is engaged in urine testing or on behalf of the Secretary or emergency personnel (e.g., firefighters and medical rescue teams), all authorized visitors and maintenance and service personnel shall be escorted at all times. The laboratory shall maintain a record that documents the dates, time of entry and exit, and purpose of entry of authorized visitors, maintenance, and service personnel accessing secured areas.

(2) Laboratories shall use chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of specimens. The date and purpose shall be documented on an appropriate chain of custody form each time a specimen is handled or transferred, and every individual in the chain shall be identified. Accordingly, authorized technicians shall be responsible for each urine specimen or aliquot in their possession and shall sign and complete chain of custody forms for those specimens or aliquots as they are received.

(b) *Receiving.* (1) When a shipment of specimens is received, laboratory personnel shall inspect each package for evidence of possible tampering and compare information on specimen bottles within each package to the information on the accompanying chain of custody forms. Any direct evidence of tampering or discrepancies in the information on specimen bottles and the specimen chain of custody forms attached to the shipment shall be immediately reported to the agency and shall be noted on the specimen chain of custody forms which shall accompany the specimens while they are in the laboratory's possession.

(2) Specimen bottles will normally be retained within the laboratory's accession area until all analyses have been completed. Aliquots and laboratory chain of custody forms shall be used by laboratory personnel for conducting initial and confirmatory tests while the original specimen and specimen chain of custody form remain in secure storage.

(c) *Short-Term Refrigerated Storage.* Specimens that do not receive an initial test within 7 days of arrival at the laboratory shall be placed in secure refrigeration units. Temperatures shall not exceed 6 °C. Emergency power equipment shall be available in case of prolonged power failure.

(d) *Specimen Processing.* Laboratory facilities for urine drug testing will normally process specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its workload. When conducting either initial or confirmatory tests, every batch shall satisfy the quality control requirements in sections 2.5 (b) and (c), respectively.

(e) *Initial Test.* (1) The initial test shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The following initial cutoff levels shall be used when screening specimens to determine whether they are negative for these five drugs or classes of drugs:

	Initial test level (ng/mL)
Marijuana metabolites	50
Cocaine metabolites	300
Opiate metabolites	[1]300
Phencyclidine	25
Amphetamines	1,000

[1] 25 ng/mL if immunoassay specific for free morphine.

(2) These test levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations. The agency requesting the authorization to include other drugs shall submit to the Secretary in writing the agency's proposed initial test methods, testing levels, and proposed performance test program.

(3) Specimens that test negative on all initial immunoassay tests will be reported negative. No further testing of these negative specimens for drugs is permitted and the specimens shall either be discarded or pooled for use in the laboratory's internal quality control program.

(4) Multiple initial tests (also known as rescreening) for the same drug or drug class may be performed provided that all tests meet all Guideline cutoffs and quality control requirements (see section 2.5(b)). Examples: a test is performed by immunoassay technique "A" for all drugs using the HHS cutoff levels, but presumptive positive amphetamines are forwarded for immunoassay technique "B" to eliminate any possible presumptive positives due to structural analogues; a valid analytical result cannot be obtained using immunoassay technique "A" and immunoassay technique "B" is used in an attempt to obtain a valid analytical result.

(f) *Confirmatory Test.* (1) All specimens identified as positive on the initial test shall be confirmed for the class(es) of drugs screened positive on the initial test using gas chromatography/mass spectrometry

(GC/MS) at the cutoff values listed in this paragraph. All confirmations shall be by quantitative analysis. Concentrations which exceed the linear region of the standard curve shall be documented in the laboratory record as "exceeds the linear range of the test."

	Confirmatory test level (ng/mL)
Marijuana metabolite[1]	15
Cocaine metabolite[2]	150
Opiates:	
Morphine	300
Codeine	300
Phencyclidine	25
Amphetamines:	
Amphetamine	500
Methamphetamine[3]	500

[1] Delta-9-tetrahydrocannabinol-9-carboxylic acid.
[2] Benzoylecgonine.
[3] Specimen must also contain amphetamine at a concentration ≥ 200 ng/mL.

(2) These test levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations. The agency requesting the authorization to include other drugs shall submit to the Secretary in writing the agency's proposed confirmatory test methods, testing levels, and proposed performance test program.

(3) Specimens that test negative on confirmatory tests shall be reported negative. No further testing of these specimens for drugs is permitted and the specimens shall either be discarded or pooled for use in the laboratory's internal quality control program.

(g) *Reporting Results.* (1) The laboratory shall report test results to the agency's MRO within an average of 5 working days after receipt of the specimen by the laboratory. Before any test result is reported (the results of initial tests, confirmatory tests, or quality control data), it shall be reviewed and the test certified as an accurate report by a certifying scientist who satisfies the requirements described by the definition in section 1.2. The report shall identify the drugs/metabolites tested for, whether positive or negative, and the cutoff for each, the specimen number assigned by the agency, and the drug testing laboratory specimen identification number.

(2) Except as otherwise provided by this subsection, the laboratory shall report as negative all specimens which are negative on the initial test or negative on the confirmatory test. Only specimens confirmed positive shall be reported positive for a specific drug. For amphetamines, to report a specimen positive for methamphetamine only, the specimen must also contain amphetamine at a concentration equal to or greater than 200 ng/mL by the confirmatory test. If this criterion is not met, the specimen must be reported as negative for methamphetamine.

(3) The MRO may request from the laboratory and the laboratory shall provide quantitation of test results. The MRO may not disclose quantitation of test results to the agency but shall report only whether the test was positive or negative.

(4) The laboratory may transmit results to the MRO by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. Results may not be provided verbally by telephone. The laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(5) The laboratory shall send only to the MRO a certified copy of the original chain of custody form signed by a certifying scientist.

(6) The laboratory shall provide to the agency official responsible for coordination of the drug-free workplace program a monthly statistical summary of urinalysis testing of Federal employees and shall not include in the summary any personal identifying information. Initial and confirmation data shall be included from test results reported within that month. Normally this summary shall be forwarded by registered or certified mail not more than 14 calendar days after the end of the month covered by the summary. The summary shall contain the following information:

Initial Testing:

(i) Number of specimens received;

(ii) Number of specimens reported out; and

(iii) Number of specimens screened positive for: Marijuana metabolites, Cocaine metabolites, Opiate metabolites, Phencyclidine, and Amphetamines.

Confirmatory Testing:

(i) Number of specimens received for confirmation;

(ii) Number of specimens confirmed positive for: Marijuana metabolite, Cocaine metabolite, Morphine, codeine, Phencyclidine, Amphetamine, and Methamphetamine. (7) The laboratory shall make available copies of all analytical results for Federal drug testing programs when requested by HHS or any Federal agency for which the laboratory is performing drug testing services.

(8) Unless otherwise instructed by the agency in writing, all records pertaining to a given urine specimen shall be retained by the drug testing laboratory for a minimum of 2 years.

(h) *Long-Term Storage.* Long-term frozen storage (−20 °C or less) ensures that positive urine specimens will be available for any necessary retest. Unless otherwise authorized in writing by the agency, drug testing laboratories shall retain and place in properly secured long-term frozen storage for a minimum of 1 year all specimens confirmed positive. Within this 1-year period an agency may request the laboratory to retain the specimen for an additional period of time. If no such request is received, the laboratory may discard the specimen after the end of 1 year, except that the laboratory shall be required to maintain any specimens under legal challenge for an indefinite period.

(i) *Retesting of a Specimen* (i.e., the reanalysis by gas chromatography/mass spectrometry of a specimen previously reported positive or the testing of Bottle B of a split specimen collection). Because some analytes deteriorate or are lost during freezing and/or storage, quantitation for a retest is not subject to a specific cutoff requirement but must provide data sufficient to confirm the presence of the drug or metabolite.

(j) *Subcontracting.* Drug testing laboratories shall not subcontract and shall perform all work with their own personnel and equipment unless otherwise authorized by the agency. The laboratory must be capable of performing testing for the five classes of drugs (marijuana, cocaine, opiates, phencyclidine, and amphetamines) using the initial immunoassay and confirmatory GC/MS methods specified in these Guidelines.

(k) *Laboratory Facilities.* (1) Laboratory facilities shall comply with applicable provisions of any State licensure requirements.

(2) Laboratories certified in accordance with Subpart C of these Guidelines shall have the capability, at the same laboratory premises, of performing initial and confirmatory tests for each drug or metabolite for which service is offered.

(l) *Inspections.* The Secretary, any Federal agency utilizing the laboratory, or any organization performing laboratory certification on behalf of the Secretary may reserve the right to inspect the laboratory at any time. Agency contracts with laboratories for drug testing, as well as contracts for collection site services, shall permit the agency to conduct unannounced inspections. In addition, prior to the

award of a contract the agency may carry out preaward inspections and evaluation of the procedural aspects of the laboratory's drug testing operation.

(m) *Documentation.* The drug testing laboratories shall maintain and make available for at least 2 years documentation of all aspects of the testing process. This 2-year period may be extended upon written notification by HHS or by any Federal agency for which laboratory services are being provided. The required documentation shall include personnel files on all individuals authorized to have access to specimens; chain of custody forms; quality assurance/quality control records; procedure manuals; all test data (including calibration curves and any calculations used in determining test results); reports; performance records on performance testing; performance on certification inspections; and hard copies of computer-generated data. The laboratory shall be required to maintain documents for any specimen under legal challenge for an indefinite period.

(n) *Additional Requirements for Certified Laboratories.*

(1) *Procedure Manual.* Each laboratory shall have a procedure manual which includes the principles of each test, preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of the methods, cutoff values, mechanisms for reporting results, controls, criteria for unacceptable specimens and results, remedial actions to be taken when the test systems are outside of acceptable limits, reagents and expiration dates, and references. Copies of all procedures and dates on which they are in effect shall be maintained as part of the manual.

(2) *Calibrators and Controls.* Laboratory calibrators and controls shall be prepared using pure drug reference materials, stock standard solutions obtained from other laboratories, or standard solutions obtained from commercial manufacturers. The calibrators and controls shall be properly labeled as to content and concentration. The standards (e.g., pure reference materials, stock standard solutions, purchased standards) shall be labeled with the following dates: When received (if applicable); When prepared or opened; when placed in service; and expiration date.

(3) *Instruments and Equipment.* (i) Volumetric pipettes and measuring devices shall be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and dilutors shall be checked for accuracy and reproducibility before being placed in service and checked periodically thereafter.

(ii) There shall be written procedures for instrument set-up and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks, and instructions for major troubleshooting and repair. Records shall be available on preventive maintenance.

(4) *Remedial Actions.* There shall be written procedures for the actions to be taken when systems are out of acceptable limits or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

(5) *Personnel Available to Testify at Proceedings.* A laboratory shall have qualified personnel available to testify in an administrative or disciplinary proceeding against a Federal employee when that proceeding is based on positive urinalysis results reported by the laboratory.

(6) *Restrictions.* The laboratory shall not enter into any relationship with an agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having an agency use a specific MRO.

Section 2.5 Quality Assurance and Quality Control

(a) *General.* Drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process including but not limited to specimen acquisition, chain of custody, security and reporting of results, initial and confirmatory testing, certification of calibrators and controls, and validation of analytical procedures. Quality assurance procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the testing process.

(b) *Laboratory Quality Control Requirements for Initial Tests.* Each analytical run of specimens to be screened shall include:

(1) Sample(s) certified to contain no drug (i.e., negative urine samples);

(2) Positive control(s) fortified with drug or metabolite;

(3) At least one positive control with the drug or metabolite at or near the threshold (cutoff);

(4) A sufficient number of calibrators to ensure and document the linearity of the assay method over time in the concentration area of the cutoff. After acceptable values are obtained for the known calibrators, those values will be used to calculate sample data;

(5) A minimum of 10 percent of the total specimens and quality control samples in each analytical run shall be quality control samples; and

(6) One percent of each run, with a minimum of at least one sample, shall be the laboratory's blind quality control samples to appear as normal samples to the laboratory analysts.

Implementation of procedures to ensure that carryover does not contaminate the testing of an donor's specimen shall be documented.

(c) *Laboratory Quality Control Requirements for Confirmation Tests.* Each analytical run of specimens to be confirmed shall include:

(1) Sample(s) certified to contain no drug (i.e., negative urine samples);

(2) Positive calibrator(s) and control(s) fortified with drug or metabolite; and

(3) At least one positive control with the drug or metabolite at or near the threshold (cutoff).

The linearity and precision of the method shall be periodically documented. Implementation of procedures to ensure that carryover does not contaminate the testing of a donor's specimen shall also be documented.

(d) Agency Blind Sample Program.

(1) Agencies shall only purchase blind quality control materials that: (a) have been certified by immunoassay and GC/MS and (b) have stability data which verifies those materials' performance over time.

(2) During the initial 90-day period of any new drug testing program, each agency shall submit blind performance test samples to each laboratory it contracts with in the amount of at least 20 percent of the total number of specimens submitted (up to a maximum of 200 blind samples) and thereafter a minimum of 3 percent blind samples (up to a maximum of 100 blind samples) submitted per quarter.

(3) Approximately 80 percent of the blind quality control samples shall be negative (i.e., certified to contain no drug) and the remaining samples shall be positive for one or more drugs per sample in a distribution such that all the drugs to be tested are included in approximately equal frequencies of challenge. The positive samples shall be spiked only with those drugs for which the agency is testing.

(4) The agency shall investigate any unsatisfactory blind performance test sample results and submit its findings to the Secretary. The Secretary shall continue the investigation to ensure that the laboratory has corrected the cause of the unsatisfactory performance test result. A report of the Secretary's

investigative findings and the corrective action taken by the laboratory shall be sent to the agency contracting officer. The Secretary shall ensure notification of the finding to all other Federal agencies for which the laboratory is engaged in urine drug testing and coordinate any necessary action.

(5) Should a false positive error occur on a blind performance test sample and the error is determined to be an administrative error (clerical, sample mixup, etc.), the Secretary shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future; and, if there is reason to believe the error could have been systematic, the Secretary may also require review and reanalysis of previously run specimens.

(6) Should a false positive error occur on a blind performance test sample and the error is determined to be a technical or methodological error, the laboratory shall submit all quality control data from the batch of specimens which included the false positive specimen. In addition, the laboratory shall retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the Responsible Person. The Secretary may require an on-site review of the laboratory which may be conducted unannounced during any hours of operation of the laboratory. The Secretary has the option of revoking (section 3.13) or suspending (section 3.14) the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

Section 2.6 Reporting and Review of Results

(a) *Medical Review Officer Shall Review Results.* An essential part of the drug testing program is the final review of results. A positive test result does not automatically identify an employee/applicant as an illegal drug user. An individual with a detailed knowledge of possible alternate medical explanations is essential to the review of results. This review shall be performed by the MRO prior to the transmission of results to agency administrative officials.

(b) *Medical Review Officer—Qualifications and Responsibilities.* The MRO shall be a licensed physician with knowledge of substance abuse disorders. The MRO may be an employee of the agency or a contractor for the agency; however, the MRO shall not be an employee or agent of or have any financial interest in the laboratory for which the MRO is reviewing drug testing results. Additionally, the MRO shall not derive any financial benefit by having an agency use a specific drug testing laboratory or have any agreement with the laboratory that may be construed as a potential conflict of interest. The role of the MRO is to review and interpret positive test results obtained through the agency's testing program. In carrying out this responsibility, the MRO shall examine alternate medical explanations for any positive test result. This action could include conducting a medical interview with the donor, review of the donor's medical history, or review of any other relevant biomedical factors. The MRO shall review all medical records made available by the donor when a confirmed positive test could have resulted from legally prescribed medication. The MRO shall not, however, consider the results of urine specimens that are not obtained or processed in accordance with these Guidelines.

(c) *Positive Test Result.* Prior to making a final decision to verify a positive test result, the MRO shall give the donor an opportunity to discuss the test result with him or her. Following verification of a positive test result, the MRO shall report the result to the agency's official designated to receive results.

(d) *Verification for Opiates; Review for Prescription Medication.* Before the MRO verifies a confirmed positive result for opiates, he or she shall determine that there is clinical evidence—in addition to the urine test—of illegal use of any opium, opiate, or opium derivative (e.g., morphine/codeine) listed in Schedule I or II of the Controlled Substances Act. This requirement does not apply if the confirmatory procedure for opiates confirms the presence of 6-monoacetylmorphine since the presence of this metabolite is proof of heroin use.

(e) *Reanalysis Authorized.* Should any question arise as to the accuracy or validity of a positive test result, only the MRO is authorized to order a retest of a single specimen or the Bottle A specimen from a split specimen collection. Such retests are authorized only at laboratories certified under these Guidelines.

(f) *Result Consistent With Legal Drug Use.* If the MRO determines there is a legitimate medical explanation for the positive test result, he or she shall take no further action and report the test result as negative.

(g) *Result Scientifically Insufficient.* Additionally, the MRO, based on review of inspection reports, quality control data, and other pertinent results, may determine that the result is scientifically insufficient for further action and declare the test specimen negative. In this situation the MRO may request a retest of the original specimen before making this decision. (The MRO may request that the retest be performed by the same laboratory or, as provided in section 2.6(e), that an aliquot of the original specimen be sent for a retest to an alternate laboratory which is certified in accordance with these Guidelines.) The laboratory shall assist in this review process as requested by the MRO by making available the individual responsible for day-to-day management of the urine drug testing laboratory or other employee who is a forensic toxicologist or who has equivalent forensic experience in urine drug testing, to provide specific consultation as required by the agency. The MRO shall report to the Secretary all negative findings based on scientific insufficiency but shall not include any personal identifying information in such reports.

(h) *Reporting Final Results.* The MRO shall report the final results of the drug tests in writing and in a manner designed to ensure confidentiality of the information.

Section 2.7 Protection of Employee Records

Consistent with 5 U.S.C. 522a(m) and 48 CFR 24.101–24.104, all laboratory contracts shall require that the contractor comply with the Privacy Act, 5 U.S.C. 522a. In addition, laboratory contracts shall require compliance with patient access and confidentiality provisions of section 503 of Public Law 100–71. The agency shall establish a Privacy Act System of Records or modify an existing system, or use any applicable Government-wide system of records to cover both the agency's and the laboratory's records of employee urinalysis results. The contract and the Privacy Act System of Records shall specifically require that employee records be maintained and used with the highest regard for employee privacy.

Section 2.8 Individual Access to Test and Laboratory Certification Results

In accordance with section 503 of Public Law 100–71, any Federal employee who is the subject of a drug test shall, upon written request, have access to any records relating to his or her drug test and any records relating to the results of any relevant certification,

review, or revocation-of-certification proceedings.

Subpart C—Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies

Section 3.1 Introduction

Urine drug testing is a critical component of efforts to combat drug abuse in our society. Many laboratories are familiar with good laboratory practices but may be unfamiliar with the special procedures required when drug test results are used in the employment context. Accordingly, the following are minimum standards to certify laboratories engaged in urine drug testing for Federal agencies. Certification, even at the highest level, does not guarantee accuracy of each result reported by a laboratory conducting urine drug testing for Federal agencies. Therefore, results from laboratories certified under these Guidelines must be interpreted with a complete understanding of the total collection, analysis, and reporting process before a final conclusion is made.

Section 3.2 Goals and Objectives of Certification

(a) *Uses of Urine Drug Testing.* Urine drug testing is an important tool to identify drug users in a variety of settings. In the proper context, urine drug testing can be used to deter drug abuse in general. To be a useful tool, the testing procedure must be capable of detecting drugs or their metabolites at concentrations indicated in sections 2.4(e) and 2.4(f).

(b) *Need to Set Standards; Inspections.* Reliable discrimination between the presence, or absence, of specific drugs or their metabolites is critical, not only to achieve the goals of the testing program but to protect the rights of the Federal employees being tested. Thus, standards have been set which laboratories engaged in Federal employee urine drug testing must meet in order to achieve maximum accuracy of test results. These laboratories will be evaluated by the Secretary or the Secretary's designee as defined in section 1.2 in accordance with these Guidelines. The qualifying evaluation will involve three rounds of performance testing plus an on-site inspection. Maintenance of certification requires participation in a quarterly performance testing program plus periodic, on-site inspections. One inspection following successful completion of a performance testing regimen is required for initial certification. This must be followed by a second inspection within 3 months, after which biannual inspections will be required to maintain certification.

(c) *Urine Drug Testing Applies Analytical Forensic Toxicology.* The possible impact of a positive test result on an individual's livelihood or rights, together with the possibility of a legal challenge of the result, sets this type of test apart from most clinical laboratory testing. In fact, urine drug testing should be considered a special application of analytical forensic toxicology. That is, in addition to the application of appropriate analytical methodology, the specimen must be treated as evidence, and all aspects of the testing procedure must be documented and available for possible court testimony. Laboratories engaged in urine drug testing for Federal agencies will require the services and advice of a qualified forensic toxicologist, or individual with equivalent qualifications (both training and experience) to address the specific needs of the Federal drug testing program, including the demands of chain of custody of specimens, security, proper documentation of all records, storage of positive specimens for later or independent testing, presentation of evidence in court, and expert witness testimony.

Section 3.3 General Certification Requirements

A laboratory must meet all the pertinent provisions of these Guidelines in order to qualify for and maintain certification under these standards.

Section 3.4 Capability to Test for Five Classes of Drugs

To be certified, a laboratory must be capable of testing for at least the following five classes of drugs: marijuana, cocaine, opiates, amphetamines, and phencyclidine using the initial immunoassay and quantitative confirmatory GC/MS methods specified in these Guidelines. The certification program will be limited to the five classes of drugs (sections 2.1(a) (1) and (2)) and the methods (sections 2.4 (e) and (f)) specified in these Guidelines. The laboratory will be surveyed and performance tested only for these methods and drugs. Certification of a laboratory indicates that any test result reported by the laboratory for the Federal Government meets the standards in these Guidelines for the five classes of drugs using the methods specified. Certified laboratories must clearly inform all unregulated, private clients when their specimens are being tested using procedures that are different from those for which the laboratory is certified (i.e., testing specimens not under the Guidelines).

Section 3.5 Initial and Confirmatory Capability at Same Site

Certified laboratories shall have the capability, at the same laboratory site, of performing both initial immunoassays and confirmatory GC/MS tests (sections 2.4 (e) and (f)) for marijuana, cocaine, opiates, amphetamines, and phencyclidine and for any other drug or metabolite for which agency drug testing is authorized (sections 2.1(a) (1) and (2)). All positive initial test results shall be confirmed prior to reporting them.

Section 3.6 Personnel

Laboratory personnel shall meet the requirements specified in section 2.3 of these Guidelines. These Guidelines establish the exclusive standards for qualifying or certifying those laboratory personnel involved in urinalysis testing whose functions are prescribed by these Guidelines. A certification of a laboratory under these Guidelines shall be a determination that these qualification requirements have been met.

Section 3.7 Quality Assurance and Quality Control

Drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process, including but not limited to specimen acquisition, chain of custody, security and reporting of results, initial and confirmatory testing, and validation of analytical procedures. Quality control procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the process of testing for drugs as specified in section 2.5 of these Guidelines.

Section 3.8 Security and Chain of Custody

Laboratories shall meet the security and chain of custody requirements provided in section 2.4(a).

Section 3.9 One-Year Storage for Confirmed Positives

All confirmed positive specimens shall be retained in accordance with the provisions of section 2.4(h) of these Guidelines.

Section 3.10 Documentation

The laboratory shall maintain and make available for at least 2 years documentation in accordance with the specifications in section 2.4(m).

Section 3.11 Reports

The laboratory shall report test results in accordance with the specifications in section 2.4(g).

Section 3.12 Certification

(a) *General.* The Secretary may certify any laboratory that meets the standards in these Guidelines to conduct urine drug testing. In addition, the Secretary may consider to be certified any laboratory that is certified by an HHS-recognized certification program in accordance with these Guidelines.

(b) *Criteria.* In determining whether to certify a laboratory or to accept the certification of an HHS-recognized certification program in accordance with these Guidelines, the Secretary shall consider the following criteria:

(1) The adequacy of the laboratory facilities;

(2) The expertise and experience of the laboratory personnel;

(3) The excellence of the laboratory's quality assurance/ quality control program;

(4) The performance of the laboratory on any performance tests;

(5) The laboratory's compliance with standards as reflected in any laboratory inspections; and

(6) Any other factors affecting the reliability and accuracy of drug tests and reporting done by the laboratory.

(c) *Corrective Action by Certified Laboratories.* A laboratory must meet all the pertinent provisions of these Guidelines in order to qualify for and maintain certification. The Secretary has broad discretion to take appropriate action to ensure the full reliability and accuracy of drug testing and reporting, to resolve problems related to drug testing, and to enforce all standards set forth in these Guidelines. The Secretary shall have the authority to issue directives to any laboratory suspending the use of certain analytical procedures when necessary to protect the integrity of the testing process; ordering any laboratory to undertake corrective actions to respond to material deficiencies identified by an inspection or through proficiency testing; ordering any laboratory to send aliquots of urine specimens to another laboratory for retesting when necessary to ensure the accuracy of testing under these Guidelines; ordering the review of results for specimens tested under the Guidelines for private sector clients to the extent necessary to ensure the full reliability of drug testing for Federal agencies; and ordering any other action necessary to address deficiencies in drug testing, analysis, specimen collection, chain of custody, reporting of results, or any other aspect of the certification program.

Section 3.13 Revocation

(a) *General.* The Secretary shall revoke certification of any laboratory certified under these provisions or accept revocation by an HHS-recognized certification program in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure the full reliability and accuracy of drug tests and the accurate reporting of test results.

(b) *Factors to Consider.* The Secretary shall consider the following factors in determining whether revocation is necessary:

(1) Unsatisfactory performance in analyzing and reporting the results of drug tests; for example, a false positive error in reporting the results of an employee's drug test;

(2) Unsatisfactory participation in performance evaluations or laboratory inspections;

(3) A material violation of a certification standard or a contract term or other condition imposed on the laboratory by a Federal agency using the laboratory's services;

(4) Conviction for any criminal offense committed as an incident to operation of the laboratory; or

(5) Any other cause which materially affects the ability of the laboratory to ensure the full reliability and accuracy of drug tests and the accurate reporting of results.

(c) *Period and Terms.* The period and terms of revocation shall be determined by the Secretary and shall depend upon the facts and circumstances of the revocation and the need to ensure accurate and reliable drug testing of Federal employees.

Section 3.14 Suspension

(a) *Criteria.* Whenever the Secretary has reason to believe that revocation may be required and that immediate action is necessary in order to protect the interests of the United States and its employees, the Secretary may immediately suspend a laboratory's certification to conduct urine drug testing for Federal agencies. The Secretary may also accept suspension of certification by an HHS-recognized certification program in accordance with these Guidelines.

(b) *Period and Terms.* The period and terms of suspension shall be determined by the Secretary and shall depend upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug testing of Federal employees.

Section 3.15 Notice

(a) *Written Notice.* When a laboratory is suspended or the Secretary seeks to revoke certification, the Secretary shall immediately serve the laboratory with written notice of the suspension or proposed revocation by facsimile mail, personal service, or registered or certified mail, return receipt requested. This notice shall state the following:

(1) The reasons for the suspension or proposed revocation;

(2) The terms of the suspension or proposed revocation; and

(3) The period of suspension or proposed revocation.

(b) *Opportunity for Informal Review.* The written notice shall state that the laboratory will be afforded an opportunity for an informal review of the suspension or proposed revocation if it so requests in writing within 30 days of the date the laboratory received the notice, or if expedited review is requested, within 3 days of the date the laboratory received the notice. Subpart D contains detailed procedures to be followed for an informal review of the suspension or proposed revocation.

(c) *Effective Date.* A suspension shall be effective immediately. A proposed revocation shall be effective 30 days after written notice is given or, if review is requested, upon the reviewing official's decision to uphold the proposed revocation. If the reviewing official decides not to uphold the suspension or proposed revocation, the suspension shall terminate immediately and any proposed revocation shall not take effect.

(d) *HHS-Recognized Certification Program.* The Secretary's responsibility under this section may be carried out by an HHS-recognized certification program in accordance with these Guidelines.

(e) *Public Notice.* The Secretary will publish in the **Federal Register** the name, address, and telephone number of any laboratory that has its certification suspended or revoked under section 3.13 or section 3.14, respectively, and the name of any laboratory which has its suspension lifted. The Secretary shall provide to any member of the public upon request the written notice provided to a laboratory that has its certification suspended or revoked, as well as the reviewing official's written decision which upholds or denies the suspension or proposed revocation under the procedures of subpart D.

Section 3.16 Recertification

Following revocation, a laboratory may apply for recertification. Unless otherwise provided by the Secretary in

the notice of revocation under section 3.13(a) or the reviewing official's decision under section 4.9(e) or 4.14(a), a laboratory which has had its certification revoked may apply for certification in accordance with this section. In order to be certified, the laboratory shall meet the criteria of section 3.12(b), as well as all other requirements of these Guidelines, including the successful participation in three cycles of performance testing (sections 3.17(b) and 3.19(a)) and a laboratory inspection (sections 3.2(b) and 3.20). Once certified, the laboratory must undergo a second inspection within three months, after which biannual inspections will be required to maintain certification (section 3.2(b)), as well as participation in the quarterly performance testing program (sections 3.1(b) and 3.17(c)).

Section 3.17 Performance Testing (PT) Requirement for Certification

(a) *An Initial and Continuing Requirement.* The PT program is a part of the initial evaluation of a laboratory seeking certification (both PT and laboratory inspection are required) and of the continuing assessment of laboratory performance necessary to maintain this certification.

(b) *Three Initial Cycles Required.* Successful participation in three cycles of testing shall be required before a laboratory is eligible to be considered for certification.

(c) *Four Challenges Per Year.* After certification, laboratories shall be challenged with at least 10 PT samples on a quarterly cycle.

(d) *Laboratory Procedures Identical for Performance Test and Routine Employee Specimens.* All procedures associated with the handling and testing of the PT samples by the laboratory shall to the greatest extent possible be carried out in a manner identical to that applied to routine laboratory specimens, unless otherwise specified.

(e) *Blind Performance Test.* Any certified laboratory shall be subject to blind PT samples (see section 2.5(d)). Performance on blind PT samples shall be at the same level as for the open or non-blind PT samples.

(f) *Reporting—Open Performance Test.* The laboratory shall report results of open PT samples to the certifying organization in the same manner as specified in section 2.4(g)(2) for routine specimens.

Section 3.18 Performance Test Samples Composition

(a) *Description of the Drugs.* PT samples shall contain those drugs and metabolites which each certified laboratory must be prepared to assay in concentration ranges that allow detection of the analytes by commonly used immunoassay screening techniques. These levels are generally in the range of concentrations which might be expected in the urine of recent drug users. For some drug analytes, the sample composition will consist of the parent drug as well as major metabolites. In some cases, more than one drug class may be included in one sample, but generally no more than two drugs will be present in any one sample in order to imitate the type of specimen which a laboratory normally encounters. For any particular PT cycle, the actual composition of kits going to different laboratories will vary but, within any annual period, all laboratories participating will have analyzed the same total set of samples.

(b) *Concentrations.* PT samples (as differentiated from blind quality control samples) shall be spiked with the drug classes and their metabolites that are required for certification (marijuana, cocaine, opiates, amphetamines, and phencyclidine) with concentration levels set by, but not limited to, one of the following schema: (1) At least 20 percent above the cutoff limit for either the initial assay or the confirmatory test, depending on which is to be evaluated; (2) below the cutoff limit as retest samples (for GC/MS quantitation); and, (3) below the cutoff limit for special purposes. Some PT samples may be identified for GC/MS assay only (retest samples). Blanks shall contain less than 2 ng/mL of any of the target drugs. These concentration and drug types may be changed periodically in response to factors such as changes in detection technology and patterns of drug use. Finally, PT samples may be constituted with interfering substances.

Section 3.19 Evaluation of Performance Testing

(a) *Initial Certification.* (1) An applicant laboratory shall not report any false positive result during PT for initial certification. Any false positive will automatically disqualify a laboratory from further consideration.

(2) An applicant laboratory shall maintain an overall grade level of 90 percent for the three cycles of PT required for initial certification, i.e., it must correctly identify and confirm 90 percent of the total drug challenges. Any laboratory which achieves a score on any one cycle of the initial certification such that it can no longer achieve a total grade of 90 percent over the three consecutive PT cycles will be immediately disqualified from further consideration.

(3) An applicant laboratory shall obtain quantitative values for at least 80 percent of the total drug challenges which are ±20 percent or ±2 standard deviations (whichever range is larger) of the calculated reference group mean. Failure to achieve 80 percent will result in disqualification.

(4) An applicant laboratory shall not obtain any quantitative values that differ by more than 50 percent from the calculated reference group mean. Any quantitative values that differ by more than 50 percent will result in disqualification.

(5) For any individual drug, an applicant laboratory shall successfully detect and quantitate in accordance with paragraphs (a)(2), (a)(3), and (a)(4) of this section at least 50 percent of the total drug challenges. Failure to successfully quantitate at least 50 percent of the challenges for any individual drug will result in disqualification.

(b) *Ongoing Testing of Certified Laboratories.* (1) *False Positives and Procedures for Dealing with Them.* No false drug identifications are acceptable for any drugs for which a laboratory offers service. Under some circumstances a false positive test may result in suspension or revocation of certification. The most serious false positives are by drug class, such as reporting THC in a blank specimen or reporting cocaine in a specimen known to contain only opiates. Misidentifications within a class (e.g., codeine for morphine) are also false positives which are unacceptable in an appropriately controlled laboratory, but they are clearly less serious errors than misidentification of a class. The following procedures shall be followed when dealing with a false positive:

(i) The agency detecting a false positive error shall immediately notify the laboratory and the Secretary of any such error.

(ii) The laboratory shall provide the Secretary with a written explanation of the reasons for the error within 5 working days. If required by paragraph (b)(1)(v) below, this explanation shall include the submission of all quality control data from the batch of specimens that included the false positive specimen.

(iii) The Secretary shall review the laboratory's explanation within 5 working days and decide what further action, if any, to take.

(iv) If the error is determined to be an administrative error (clerical, sample mixup, etc.), the Secretary may direct the laboratory to take corrective action to minimize the occurrence of the particular error in the future and, if

there is reason to believe the error could have been systematic, may require the laboratory to review and reanalyze previously run specimens.

(v) If the error is determined to be a technical or methodological error, the laboratory shall submit to the Secretary all quality control data from the batch of specimens which included the false positive specimen. In addition, the laboratory shall retest all specimens analyzed positive by the laboratory from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the laboratory's responsible person. Depending on the type of error which caused the false positive, this retesting may be limited to one analyte or may include any drugs a laboratory certified under these Guidelines must be prepared to assay. The laboratory shall immediately notify the agency if any result on a specimen that has been retested must be corrected because the criteria for a positive are not satisfied. The Secretary may suspend or revoke the laboratory's certification for all drugs or for only the drug or drug class in which the error occurred. However, if the case is one of a less serious error for which effective corrections have already been made, thus reasonably assuring that the error will not occur again, the Secretary may decide to take no further action

(vi) During the time required to resolve the error, the laboratory shall remain certified but shall have a designation indicating that a false positive result is pending resolution. If the Secretary determines that the laboratory's certification must be suspended or revoked, the laboratory's official status will become "Suspended" or "Revoked" until the suspension or revocation is lifted or any recertification process is complete.

(2) *Requirement to Identify and Confirm 90 Percent of Total Drug Challenges.* In order to remain certified, laboratories must successfully complete four cycles of PT per year. Failure of a certified laboratory to maintain a grade of 90 percent over the span of two consecutive PT cycles, i.e., to identify 90 percent of the total drug challenges and to correctly confirm 90 percent of the total drug challenges, may result in suspension or revocation of certification.

(3) *Requirement to Quantitate 80 Percent of Total Drug Challenges at ±20 Percent or ±2 Standard Deviations.* Quantitative values obtained by a certified laboratory for at least 80 percent of the total drug challenges must be ±20 percent or ±2 standard deviations (whichever range is larger) of the appropriate reference or peer group mean as measured over two consecutive PT cycles.

(4) *Requirement to Quantitate Within 50 Percent of Calculated Reference Group Mean.* After achieving certification a laboratory is permitted one quantitative result differing by more than 50% from the target value within two consecutive cycles of PT. More than one error of this type within two consecutive PT cycles may result in a suspension or proposed revocation.

(5) *Requirement to Successfully Detect and Quantitate 50 Percent of the Total Drug Challenges for Any Individual Drug.* For any individual drug, a certified laboratory must successfully detect and quantitate in accordance with paragraphs (b)(2),(b)(3), and (b)(4) of this section at least 50 percent of the total drug challenges.

(6) *Procedures When Requirements in Paragraphs (b)(2)—(b)(5) of this Section Are Not Met.* If a certified laboratory fails to maintain a grade of 90 percent over the span of two consecutive PT cycles after initial certification as required by paragraph (b)(2) of this section or if it fails to successfully quantitate results as required by paragraphs (b)(3),(b)(4), or (b)(5) of this section, the laboratory shall be immediately informed that its performance fell under the 90 percent level or that it failed to quantitate test results successfully and how it failed to quantitate successfully. The laboratory shall be allowed 5 working days in which to provide any explanation for its unsuccessful performance, including administrative error or methodological error, and evidence that the source of the poor performance has been corrected. The Secretary may revoke or suspend the laboratory's certification or take no further action, depending on the seriousness of the errors and whether there is evidence that the source of the poor performance has been corrected and that current performance meets the requirements for a certified laboratory under these Guidelines. The Secretary may require that additional performance tests be carried out to determine whether the source of the poor performance has been removed. If the Secretary determines to suspend or revoke the laboratory's certification, the laboratory's official status will become "Suspended" or "Revoked" until the suspension or revocation is lifted or until any recertification process is complete.

(c) *80 Percent of Participating Laboratories Must Detect Drug.* A laboratory's performance shall be evaluated for all samples for which drugs were spiked at concentrations above the specified performance test level unless the overall response from participating laboratories indicates that less than 80 percent of them were able to detect a drug.

(d) *Participation Required.* Failure to participate in a PT cycle or to participate satisfactorily may result in suspension or revocation of certification.

Section 3.20 Inspections

(a) *Frequency.* Prior to laboratory certification under these Guidelines and at least twice a year after certification, a team of three qualified inspectors, at least two of whom have been trained as laboratory inspectors, shall conduct an on-site inspection of laboratory premises. Inspections shall document the overall quality of the laboratory setting for the purposes of certification to conduct urine drug testing. Inspection reports may also contain recommendations to the laboratory to correct deficiencies noted during the inspection.

(b) *Inspectors.* The Secretary shall establish criteria for the selection of inspectors to ensure high quality, unbiased, and thorough inspections. The inspectors shall perform inspections consistent with the guidance provided by the Secretary. Inspectors shall document the overall quality of the laboratory's drug testing operation.

(c) *Inspection Performance.* The laboratory's operation shall be consistent with good forensic laboratory practice and shall be in compliance with these Guidelines. It is the laboratory's responsibility to correct deficiencies identified during the inspection and to have the knowledge, skill, and expertise to correct deficiencies consistent with good forensic laboratory practice. Consistent with sections 3.13 and 3.14, deficiencies identified at inspections may be the basis for suspending or revoking a laboratory's certification.

Section 3.21 Results of Inadequate Performance

Failure of a laboratory to comply with any aspect of these Guidelines may lead to revocation or suspension of certification as provided in sections 3.13 and 3.14 of these Guidelines.

Section 3.22 Listing of Certified Laboratories

A **Federal Register** listing of laboratories certified by HHS will be updated and published periodically. Laboratories which are in the applicant stage of HHS certification are *not* to be

considered as meeting the minimum requirements in these Guidelines. A laboratory is not certified until HHS has sent the laboratory an HHS letter of certification.

Subpart D—Procedures for Review of Suspension or Proposed Revocation of a Certified Laboratory

Section 4.1 Applicability

These procedures apply when:

(a) The Secretary has notified a laboratory in writing that its certification to perform urine drug testing under these Mandatory Guidelines for Federal Workplace Drug Testing Programs has been suspended or that the Secretary proposes to revoke such certification.

(b) The laboratory has, within 30 days of the date of such notification or within 3 days of the date of such notification when seeking an expedited review of a suspension, requested in writing an opportunity for an informal review of the suspension or proposed revocation.

Section 4.2 Definitions

Appellant: Means the laboratory which has been notified of its suspension or proposed revocation of its certification to perform urine drug testing and has requested an informal review thereof.

Respondent: Means the person or persons designated by the Secretary in implementing these Guidelines (currently the National Laboratory Certification Program is located in the Division of Workplace Programs, Substance Abuse and Mental Health Services Administration).

Reviewing Official: Means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more of his or her employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

Section 4.3 Limitation on Issues Subject to Review

The scope of review shall be limited to the facts relevant to any suspension or proposed revocation, the necessary interpretations of those facts, the Mandatory Guidelines for Federal Workplace Drug Testing Programs, and other relevant law. The legal validity of the Mandatory Guidelines shall not be subject to review under these procedures.

Section 4.4 Specifying Who Represents the Parties

The appellant's request for review shall specify the name, address, and phone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and phone number of the respondent's representative.

Section 4.5 The Request for Informal Review and the Reviewing Official's Response

(a) Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension or proposed revocation, a brief statement of why the decision to suspend or propose revocation is wrong, and the appellant's request for an oral presentation, if desired.

(b) Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

Section 4.6 Abeyance Agreement

Upon mutual agreement of the parties to hold these procedures in abeyance, the reviewing official will stay these procedures for a reasonable time while the laboratory attempts to regain compliance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs or the parties otherwise attempt to settle the dispute. As part of an abeyance agreement, the parties can agree to extend the time period for requesting review of the suspension or proposed revocation. If abeyance begins after a request for review has been filed, the appellant shall notify the reviewing official at the end of the abeyance period advising whether the dispute has been resolved. If the dispute has been resolved, the request for review will be dismissed. If the dispute has not been resolved, the review procedures will begin at the point at which they were interrupted by the abeyance agreement with such modifications to the procedures as the reviewing official deems appropriate.

Section 4.7 Preparation of the Review File and Written Argument

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) *Appellant's Documents and Brief.* Within 15 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification is wrong (appellant's brief).

(b) *Respondent's Documents and Brief.* Within 15 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification to perform urine drug testing, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension or proposed revocation (respondent's brief).

(c) *Reply Briefs.* Within 5 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) *Cooperative Efforts.* Whenever feasible, the parties should attempt to develop a joint review file.

(e) *Excessive Documentation.* The reviewing official may take any appropriate step to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

Section 4.8 Opportunity for Oral Presentation

(a) *Electing Oral Presentation.* If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the

decision-making process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) *Presiding Official.* The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) *Preliminary Conference.* The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; time allotted for each witness and the hearing altogether; scheduling the hearing; and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at his or her discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) *Time and Place of Oral Presentation.* The presiding official will attempt to schedule the oral presentation within 30 days of the date appellant's request for review is received or within 10 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) *Conduct of the Oral Presentation.*

(1) *General.* The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more of his or her employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) *Burden of Proof/Standard of Proof.* In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend or propose revocation is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is wrong.

(3) *Admission of Evidence.* The rules of evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the prehearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) *Motions.* The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) *Transcripts.* The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of Justice or Making of False Statements.* Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1505 or 1001.

(g) *Post-hearing Procedures.* At his or her discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

Section 4.9 Expedited Procedures for Review of Immediate Suspension

(a) *Applicability.* When the Secretary notifies a laboratory in writing that its certification to perform urine drug testing has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 3 days of the date the laboratory received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is wrong, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing Official's Response.* As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) *Review File and Briefs.* Within 7 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following: (1) a review file containing essential documents relevant to the review, tabbed, indexed, and organized chronologically, and (2) a written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral Presentation.* If an oral presentation is requested by the appellant or otherwise granted by the reviewing official, the presiding official will attempt to schedule the oral presentation within 7–10 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a pre-hearing conference in accordance with section 4.8(c) and will conduct the oral presentation in accordance with the procedures of sections 4.8 (e), (f), and (g).

(e) *Written Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7–10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in section 4.14 will apply.

(f) *Transmission of Written Communications.* Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be by facsimile or overnight mail.

Section 4.10 Ex parte Communications

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

Section 4.11 Transmission of Written Communications by Reviewing Official and Calculation of Deadlines

(a) Because of the importance of a timely review, the reviewing official should normally transmit written

communications to either party by facsimile or overnight mail in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) In counting days, include Saturdays, Sundays, and holidays. However, if a due date falls on a Saturday, Sunday, or Federal holiday, then the due date is the next Federal working day.

Section 4.12 Authority and Responsibilities of Reviewing Official

In addition to any other authority specified in these procedures, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of these procedures.

Section 4.13 Administrative Record

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

Section 4.14 Written Decision

(a) *Issuance of Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation. The decision will set forth the reasons for the decision and describe the basis therefor in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of Decision.* The reviewing official will attempt to issue his or her decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public Notice.* If the suspension and proposed revocation are upheld, the revocation will become effective immediately and the public will be notified by publication of a notice in the **Federal Register**. If the suspension and proposed revocation are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the **Federal Register**.

Section 4.15 Court Review of Final Administrative Action; Exhaustion of Administrative Remedies

Before any legal action is filed in court challenging the suspension or proposed revocation, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal Law. The reviewing official's decision, under section 4.9(e) or 4.14(a), constitutes final agency action and is ripe for judicial review as of the date of the decision.

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